IGI LABORATORIES, INC
Form 424B3
May 15, 2013
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PROSPECTUS

IGI LABORATORIES, INC.

2,780,654 Shares

Common Stock

This prospectus relates to the resale from time to time of up to 2,780,654 shares of our common stock, par value $0.01 per share, by the selling stockholder identified in this prospectus. The shares of common stock offered under this prospectus by the selling stockholder were issued to Amzak Capital Management, LLC, or Amzak, pursuant to a Securities Purchase Agreement between us and Amzak, dated December 20, 2012, a warrant we issued to Amzak on that date and a warrant we issued to Amzak on December 31, 2012.

We are not selling any shares of our common stock under this prospectus and we will not receive any of the proceeds from the sale of shares by the selling stockholder. The selling stockholder has advised us that it will sell the common stock from time to time in the open market, on the NYSE MKT or on any national securities exchange or automated interdealer quotation system on which our common stock is then listed or quoted, in privately negotiated transactions or a combination of these methods, at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or otherwise as described under Plan of Distribution on page 19. No underwriter or other person has been engaged to facilitate the sale of shares of our common stock in this offering. We are paying the cost of registering the shares of our common stock covered by this prospectus as well as various related expenses. The selling stockholder is responsible for all selling commissions, transfer taxes and other costs related to the offer and sale of its shares of our common stock.

Our common stock is listed on NYSE MKT under the symbol IG. On May 8, 2013, the last reported sales price for our common stock was $1.88 per share.

INVESTING IN OUR COMMON STOCK INVOLVES RISKS. YOU SHOULD CAREFULLY CONSIDER THE RISK FACTORS INCLUDED IN THIS PROSPECTUS BEGINNING ON PAGE 5 AND THE RISK

FACTORS INCLUDED IN OUR ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2012, AND ANY SUBSEQUENTLY FILED PERIODIC REPORTS THAT ARE INCORPORATED BY REFERENCE HEREIN, BEFORE YOU DECIDE TO INVEST.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is May 13, 2013.

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FORWARD-LOOKING STATEMENTS

This prospectus, any supplements to this prospectus and other documents that are and will be incorporated into this prospectus contain statements that involve expectations, plans or intentions (such as those relating to future business or financial results, new products or services, or management strategies). These statements are forward-looking and are subject to risks and uncertainties, so actual results may vary materially. You can identify these forward-looking statements by words such as may, should, expect, anticipate, believe, estimate, intend, plan and other similar expressions. You should consider our forward-looking statements in light of the risks discussed under the heading Risk Factors below and in documents incorporated herein by reference, including our consolidated financial statements, related notes and other financial information appearing in our other filings and documents incorporated herein by reference. Given these risks and uncertainties, we caution you not to place undue reliance on such forward-looking statements. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our business, financial condition or results of operations. Except as required by law, we undertake no obligation to publicly revise our forward-looking statements to reflect events or circumstances that arise after the date of this prospectus or any applicable prospectus supplement or the respective dates of documents incorporated herein or therein that include forward-looking statements.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus and any supplements to this prospectus carefully, including the section entitled Risk Factors and the documents that we incorporate by reference into this prospectus or any such supplements, before making an investment decision.

Our Business

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

Our strategy is based on three initiatives:

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

Increasing our current contract manufacturing and development business; and,

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

In December, 2012, we completed the implementation of our commercial infrastructure and launched our first generic topical pharmaceutical products in the IGI label. We have filed nine Abbreviated New Drug Applications, or ANDAs,

with the United States Food and Drug Administration, or US FDA. We will continue to expand our presence in the generic topical pharmaceutical market through the filing of additional ANDAs with the US FDA and the subsequent launch of products as these applications are approved. Our target is to file six ANDAs per year through our internal research and development program. We will also seek to license or acquire further products, intellectual property, or ANDAs to expand our portfolio. On February 1, 2013, we acquired assets and intellectual property, including an ANDA, for econazole nitrate cream 1%.

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

We perform all of our product development and manufacturing at our facility in Buena, New Jersey. Our head office, product development laboratories, and manufacturing facility are located at 105 Lincoln Avenue, Buena, New Jersey. Our telephone number is 856-697-1441 and our website is http://www.igilabs.com. Information contained on our website is not incorporated into this prospectus.

Recent Developments

On February 1, 2013, we entered into an Asset Purchase Agreement, or the purchase agreement, with Prasco, LLC, an Ohio limited liability company, or Prasco pursuant to which we purchased from Prasco assets associated with Econazole Nitrate Cream 1%, or the Product. Econazole Nitrate Cream 1% which is available in 15g, 30g, and 85g tubes has United States Food and Drug Administration approved indications for the treatment of tinea pedis, tinea cruris, and tinea corporis as well as the treatment of cutaneous candidiasis and tinea versicolor. In consideration for the purchase of the assets pursuant to the purchase agreement, we paid Prasco $1.4 million in cash and will be required to pay an additional aggregate of $400,000 upon the occurrence of certain milestone events, or the milestone payment. The milestone payment is secured by a first-priority security interest in the acquired assets under the purchase agreement. Under and subject to the terms and conditions of the purchase agreement, Prasco will continue to distribute the product during a six-month period following the closing of the purchase agreement or for a shorter period if we have completed the technical transfer of the product and begun manufacturing the product under our own label.

On February 15, 2013, we entered into a three-year agreement with Juventio, LLC to manufacture and supply finished dose forms of certain cosmetic and OTC products and formulations owned and developed by us. These products utilize innovative encapsulation technology trademarked as Novasome® for which we currently holds an exclusive license. Juventio is a New Jersey based company that distributes premium non-prescription health products, in partnership with healthcare professionals.

The Offering

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

We are registering an aggregate of 2,780,654 shares of common stock to satisfy the registration rights we granted to Amzak pursuant to the terms of registration rights agreements, or the registration rights agreements, we entered into with Amzak on December 20, 2012 and December 21, 2012, relating to the registration of the shares, the warrants and the shares of common stock issuable upon the exercise of the warrants. All of the shares of common stock covered by this prospectus are being offered by Amzak.

We are not selling any securities under this prospectus or any of its supplements and will not receive any of the proceeds from the sale of shares by the selling stockholder.

RISK FACTORS

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

Risks Related to our Business

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

Our expenses have exceeded our revenue in each of the last eight years, and no net income has been available to common stockholders during each of these years. As of December 31, 2012, our stockholders equity was $6.4 million and we had an accumulated deficit of $43.4 million. Our future profitability depends on revenue exceeding expenses, but we cannot assure you that this will occur. If we do not become profitable or continue to raise external financing, we could be forced to curtail operations and sell or liquidate our business, and you could lose some or all of your investment.

We face intense competition in the consumer products business.

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

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

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

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

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

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

other generic drug manufacturers.

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

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

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

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

Operating our business and maintaining our growth efforts will require additional cash outlays and capital expenditures. If cash on hand and cash generated from operations are not sufficient to meet our cash requirements, we will need to seek additional capital, potentially through debt or equity financings, to fund our growth. We cannot assure you that we will be able to raise needed cash on terms acceptable to us or at all. Financings may be on terms that are dilutive or potentially dilutive to our stockholders, and the prices at which new investors would be willing to purchase our securities may be lower than the current price per share of our common stock. The holders of new securities may also have rights, preferences or privileges which are senior to those of existing holders of common stock. If new sources of financing are required, but are insufficient or unavailable, we will be required to modify our growth and operating plans based on available funding, if any, which would harm our ability to grow our business or even stay in business. We had $2.0 million available funds under an existing line of credit at December 31, 2012. We drew down an additional $1.0 million in principal amount in February of 2013.

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

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

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

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

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

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

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

Affordable high quality raw materials and packaging components are essential to our business due to the nature of the products we manufacture. Raw materials and packaging components are generally available from multiple suppliers.

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

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

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

Our products, and the raw materials used to make those products, generally have limited shelf lives. Our inventory levels are based, in part, on expectations regarding future sales. We may experience build-ups in inventory if sales slow. Any significant shortfall in sales may result in higher inventory levels of raw materials and finished products, thereby increasing the risk of inventory spoilage and corresponding inventory write-downs and write-offs, which may materially and adversely affect our results of operations. Additionally, labeling changes required for regulatory compliance could render packaging inventories obsolete. Cargo thefts and/or diversions and economically or maliciously motivated product tampering in store shelves may be experienced from time to time, causing unexpected shortages.

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

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

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

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

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

Our operations and properties are also subject to a wide variety of increasingly complex and stringent federal, state and local environmental laws and regulations, including those governing the remediation of contaminated soil and groundwater. Such environmental laws may apply to conditions at properties and facilities presently or formerly

owned or operated by us, as well as to conditions at properties at which wastes or other contamination attributable to us have been sent or otherwise come to be located. Two of our facilities are currently undergoing remediation of environmental contamination. The total estimated costs for the clean-up and remediation is $739,000, of which approximately $25,000 remains accrued as of December 31, 2012. The remediation and disposal on the second facility was completed in 2011 at a cost of approximately $61,000. We received a No Further Action Letter from the New Jersey Department of Environmental Protection on May 23, 2011. Based on information provided to us from our environmental consultants and what is known to date, we believe the reserves are sufficient for the remaining remediation of the environmental contamination. There is a possibility, however, that the remediation costs may exceed our estimates. In addition, we can give no assurance that the future cost of compliance with existing environmental laws will not give rise to additional significant expenditures or liabilities that would be material to us. Future events, such as new information, changes in existing environmental laws or their interpretation, and more vigorous enforcement policies of federal, state or local regulatory agencies, may have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

Product recalls could harm our business.

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

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

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

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

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

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

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

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

the pending patent applications we have filed or may file, or to which we have exclusive rights, may not result in issued

patents, or may take longer than we expect to result in issued patents;

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

we may be subject to interference proceedings;

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

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

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

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

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

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

enforcement of patents is complex, uncertain and expensive.

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

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

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

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

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

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

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

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

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

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

discontinue the use of the infringing technology;

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

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

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

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

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

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

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

Economic conditions could severely impact us.

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

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

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

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

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

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

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

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

Risks Related to Our Securities

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

For the twelve months ended December 31, 2012, the average daily trading volume of our shares of common stock on the NYSE MKT was approximately 13,402 shares. As a result of our relatively small public float, our shares of common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our shares of common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.

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

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

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

As a public company, we are required to comply with the periodic reporting obligations of the Exchange Act including preparing annual reports, quarterly reports and current reports. Our failure to prepare and disclose this information in a timely manner could subject us to penalties under federal securities laws, expose us to lawsuits and restrict our ability to access financing. In addition, we are required under applicable law and regulations to integrate our systems of disclosure controls and procedures and internal control over financial reporting. Our management assessed our existing disclosure controls and procedures as of December 31, 2012 and December 31, 2011, and our management concluded that our disclosure controls and procedures were effective as of such times.

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

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

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

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

Our current principal stockholders, directors and executive officers beneficially own approximately 64.7% of our outstanding capital stock entitled to vote. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

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

Our stock price is, and we expect it to remain, volatile, which could limit investors ability to sell stock at a profit. During the last two fiscal years, our stock price has closed at a low of $0.94 in the second quarter of 2012 and a high of $1.80 in the first quarter of 2011. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by our competitors or us;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the U.S. and foreign countries;
- economic or other crises, especially given the recent financial deterioration in the markets in which we compete, and other external factors;
- stock market price and volume fluctuations of other publicly traded companies and, in particular, those that are in the cosmetic, pharmaceutical and consumer products industry;
- actual or anticipated sales of our common stock, including sales by our directors, officers or significant stockholders;
- period-to-period fluctuations in our revenues and other results of operations;
- speculation about our business in the press or the investment community;
- changes in financial estimates by us or by any securities analysts who might cover our stock; and
- sales of our common stock.

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

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

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

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

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

USE OF PROCEEDS

We will not receive any proceeds from the sale or other disposition by the selling stockholder of the shares of our common stock covered hereby. All proceeds from the sale of the common stock will be paid directly to the selling stockholder.

The selling stockholder will pay any underwriting discounts and commissions and expenses incurred by the selling stockholder for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholder in disposing of these shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration fees, listing fees of NYSE MKT and fees and expenses of our counsel and our accountants.

DIVIDEND POLICY

We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Consequently, stockholders will need to sell shares of our common stock to realize a return on their investment, if any.

THE OFFERING

The following is a summary of the material provisions of the agreements executed by us and Amzak in connection with the offering covered by this prospectus:

Purchase Agreement. On December 21, 2012, we closed a $2,000,000 private placement with Amzak. Pursuant to the terms of a Securities Purchase Agreement entered into with Amzak (the Purchase Agreement) pursuant to which we issued to Amzak (i) 1,965,740 shares of our common stock, par value $0.01 per share, held in treasury (the Shares), and (ii) a ten-year warrant to purchase up to an aggregate of 387,201 shares of the Company common stock, with an exercise price of $0.01 per share (individually, the Warrants, and collectively with the Shares, the Registrable Shares). The Warrants, which were immediately exercisable, were exercised to 387,201 shares of our common stock by Amzak on December 27, 2012 for an aggregate of $3,872 proceeds to us.

We issued the Registrable Shares in reliance upon the exemption from registration provided for under Section 4(2) of the Securities Act and Rule 506 of Regulation D thereunder.

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

Settlement Agreement. As of December 31, 2012, we entered into a settlement agreement with Amzak in connection with a common stock purchase warrant we issued to Amzak on December 21, 2012 under which we issued a ten-year warrant to purchase up to 427,713 shares of our common stock, with an exercise price of $0.55 per share. The warrants were exercised in full on February 8, 2013. For additional information, please refer to the summary of prior transactions with the selling stockholder described under the section entitled Selling Stockholder.

The registration statement of which this prospectus is a part registers, for resale, 2,780,654 shares of our common stock under the Securities Act of 1933, or the Securities Act.

SELLING STOCKHOLDER

The selling stockholder named in this prospectus acquired shares of our common stock in connection with the offering completed on December 21, 2012. In connection with the offering, we granted to the selling stockholder registration rights pursuant to which we agreed to file with the SEC a registration statement on Form S-3, of which this prospectus forms a part, with respect to the resale or other disposition of the Registrable Shares. The Registrable Shares being offered for resale by this prospectus may be sold or otherwise disposed of from time to time by the selling stockholder on NYSE MKT, in privately negotiated transactions or otherwise as further described under the Plan of Distribution set forth on page 19. We have also agreed to prepare and file amendments and supplements to the registration statement to the extent necessary to keep the registration statement effective for the period of time required under our agreement with the selling stockholder. Further, we have agreed to pay the selling stockholder specified cash payments as partial liquidated damages in the event the Initial Registration Statement is not declared effective by the Securities and Exchange Commission within nine months of December 20, 2012.

The table set forth below presents the following information regarding the selling stockholder and the shares of common stock that the selling stockholder may offer and sell from time to time under this prospectus:

The Number of Shares of Common Stock Beneficially Owned Prior to the Offering represents the number of shares of common stock beneficially owned prior to the offering for the selling stockholder, which includes (i) all shares held by such selling stockholder prior to the date hereof, and (ii) shares issuable upon all options or other derivative securities held by the selling stockholder that are exercisable within 60 days of April 30, 2013.

The Maximum Number of Shares of Common Stock Being Offered represents all of the shares of common stock that the selling stockholder may offer under this prospectus.

The Number of Shares of Common Stock Beneficially Owned After Offering assumes that the selling stockholder sells all of the shares it may offer under this prospectus.

The Percentage of Shares of Common Stock Beneficially Owned After the Offering is based on 42,805,032 shares of our common stock issued and outstanding as of April 30, 2013.

Beneficial ownership is determined in accordance with the rules of the SEC, and is based upon information provided by the selling stockholder on a Schedule 13G filed by the selling stockholder on January 30, 2013 and other public documents filed with the SEC. Unless otherwise indicated below, to our knowledge, the selling stockholder named in this table has sole voting and investment power with respect to its shares of common stock. The inclusion of any shares in this table does not constitute an admission of beneficial ownership for the person named below.

Except as noted in the footnotes below, the selling stockholder has not held any position or office with us or our affiliates within the last three years or has had a material relationship with us or any of our predecessors or affiliates within the past three years, other than as a result of the ownership of our shares or other securities.

The selling stockholder may sell some, all or none of the shares of common stock offered by this prospectus. We currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares of common stock being offered hereunder other than the definitive agreements pursuant to which the selling stockholder received in connection with the offering. The shares offered by this prospectus may be offered from time to time by the selling stockholder. Accordingly, for purposes of this table, we have assumed that, after completion of the offering, the only shares that will continue to be held by the selling stockholder are those shares that do not have registration. The selling stockholder may have sold or transferred, in transactions exempt from the registration requirements of the Securities Act, some or all of its shares of common stock since the date on which the information in the table below is presented. Information about the selling stockholder may change over time.

The following table sets forth, to our knowledge, information about the selling stockholder as of April 30, 2013.

Name of Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to the Offering	Maximum Number of Shares of Common Stock Being Offered	Number of Shares of Common Stock Beneficially Owned After Offering	Percentage of Shares of Common Stock Beneficially Owned After Offering
Amzak Capital Management, LLC(1)	4,261,076	2,780,654	1,480,422	3.47%

(1) Each of Michael D. Kazma and Gerry Kazma is a manager of Amzak and may be deemed to share voting and investment power with respect to the shares of common stock held by Amzak. Each of Michael D. Kazma and Gerry Kazma disclaims beneficial ownership of any shares of common stock owned by the others. Includes, 10,000 shares of common stock held by Michael D. Kazma.

The following is a summary of prior securities transactions we entered into with the selling stockholder:

Amzak Capital Management LLC. On December 21, 2010, we entered into a Credit Agreement (the Credit Agreement) with Amzak Capital Management, LLC, or Amzak, pursuant to which Amzak agreed to extend a $3,000,000 credit facility to us, which we refer to as the Financing. In connection with the Credit Agreement, we issued to Amzak a ten-year warrant to purchase certain shares of our common stock at an exercise price of $0.01 per share, which we refer to as the Amzak Warrant. The Amzak Warrant is immediately exercisable for 881,331 shares of our common stock, or the Initial Warrant Shares, with the remaining shares of common stock representing 1% of our fully diluted shares as of July 1, 2012, or the Conditional Warrant Shares, becoming immediately exercisable if we fail to achieve certain milestones related to our product development or financial growth. As of March 6, 2013, Amzak exercised all of the warrants to purchase our shares common stock held by it. In connection with the Financing, we entered into two registration rights agreements with Amzak, one for the Initial Warrant Shares, which we refer to as the Initial Registration Statement, and another for the Conditional Warrant Shares, which we refer to as the Conditional Registration Statement, pursuant to which we agreed to register for resale the Initial Warrant Shares and the Conditional Warrant Shares into which the Amzak Warrant is exercisable. The Conditional Warrant Shares were issued to Amzak under the settlement agreement, dated as of December 31, 2012, and were exercised in full into 427,713 shares of common stock on February 8, 2013, which shares are being registered for resale in this registration statement. We issued the Amzak Warrant in reliance upon the exemption from registration provided for under Section 4(2) of the Securities Act of 1933, as amended, or the Securities Act, and Rule 506 of Regulation D thereunder. We filed a registration statement covering the resale of these shares on April 20, 2011 (File No. 333-173615) and such registration statement was declared effective by the Commission on May 11, 2011.

On December 8, 2010, we consummated the sale of 5,909,087 shares of our common stock to several accredited investors as defined in Rule 501 of Regulation D under the Securities at a price of $1.10 per share, or an aggregate of approximately $6,500,000 (the December 2010 Private Placement). Amzak purchased 909,091 shares of our common stock (the Private Placement Shares) in the December 2010 Private Placement for a total purchase price of approximately $1,000,000. The shares were issued in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act and Rule 506 promulgated thereunder. In connection with the December 2010 Private Placement, we entered into a registration rights agreement with each of these investors pursuant to which we granted the investors specified registration rights relating to the common stock purchased in the offering. We filed a registration statement covering the resale of these shares on March 29, 2011 (File No. 333-173148) and such registration statement was declared effective by the Commission on April 8, 2011.

Based on information we received from Amzak, it does not have an existing short position in our common stock.

PLAN OF DISTRIBUTION

We are registering shares of common stock on behalf of the selling stockholder. Selling stockholder includes donees, pledgees, transferees or successors-in-interest selling securities received from the named selling stockholder as a gift, pledge, partnership distribution or other non-sale related transfer after the date of this prospectus.

The selling stockholder may, from time to time, sell any or all of its shares of common stock on the NYSE MKT or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholder to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholder may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholder (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA NASD Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASD IM-2440.

In connection with the sale of the common stock or interests therein, the selling stockholder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholder may also sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholder may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholder and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

We are required to pay certain fees and expenses we incur incident to the registration of the shares. We have agreed to indemnify the selling stockholder against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because a selling stockholder may be deemed to be underwriters within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholder.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling stockholder without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for us to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholder will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the selling stockholder or any other person. We will make copies of this prospectus available to the selling stockholder and have informed the selling stockholder of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

LEGAL MATTERS

The validity of the shares of our common stock offered by this prospectus will be passed upon for us by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

EXPERTS

The financial statements of IGI Laboratories, Inc. as of December 31, 2012 and 2011, and for each of the years in the two-year period ended December 31, 2012 which were included in our Annual Report on Form 10-K for the year ended December 31, 2012, have been incorporated by reference herein and in the registration statement in reliance upon the report of EisnerAmper LLP, an independent registered public accounting firm, upon the authority of said

firms as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement on Form S-3 that we filed with the SEC. We are a public company and file proxy statements and annual, quarterly and current reports and other information with the SEC. You can inspect and copy the registration statement as well as the reports, proxy statements and other information we have filed with the SEC at the public reference room maintained by the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can call the SEC at 1-800-732-0330 for further information about the public reference room. We are also required to file electronic versions of these documents with the SEC, which may be accessed from the SEC s website at http://www.sec.gov.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference certain of our publicly-filed documents into this prospectus, which means that information included in those documents is considered part of this prospectus. Information that we file with the SEC after the effective date of this prospectus will automatically update and supersede this information. We incorporate by reference the documents listed below, any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the initial filing of the registration statement and prior to the effectiveness of the registration statement and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and before the termination of the final offering of securities under this prospectus.

The following documents filed with the SEC are incorporated by reference in this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2012, filed on March 28, 2013, as amended by Amendment No. 1 to Form 10-K filed on April 30, 2013;
- our Current Report on Form 8-K, filed on February 7, 2013;
- our Definitive Proxy Statement on Form DEF 14A filed on May 3, 2013;
- the description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on June 9, 1988, including any amendments or reports filed thereafter for the purpose of updating such description in which there is described the terms, rights and provisions applicable to our common stock; and
- all filings we make with the SEC pursuant to the Exchange Act after the date of this prospectus and before termination of this offering.

We do not incorporate by reference any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K in any future filings, unless specifically stated otherwise in such filings.

You may access our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to any of these reports, free of charge on the SEC s website. We do not consider information contained on, or that can be accessed through, our website to be part of this prospectus.

In addition, we will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, other than exhibits to those documents. You should direct any requests for documents to our Chief Executive Officer, c/o IGI Laboratories, Inc., 105 Lincoln Avenue, Buena, New Jersey, 08310, (856)

697-1441.

You should rely only on the information contained in this prospectus, including information incorporated by reference herein. We have not authorized anyone to provide you with information different from that contained in this prospectus or any prospectus supplement. This prospectus is not an offer of these securities in any jurisdiction where an offer and sale is not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.