

IGI LABORATORIES, INC  
Form 10-K  
March 16, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended **December 31, 2014**

**OR**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: **001-08568**

**IGI Laboratories, Inc.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

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

**01-0355758**

*(I.R.S. Employer Identification No.)*

**105 Lincoln Ave., Buena, NJ**

*(Address of principal executive offices)*

**08310**

*(Zip Code)*

Registrant's telephone number, including area code **(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 Per Share	NYSE MKT

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 mark 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. (Check one):

Large accelerated filer  Accelerated filer

Non-accelerated filer  [Do not check if a smaller reporting company]

Smaller reporting company

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold, as of the last business day of the registrant's most recently completed second fiscal quarter was \$158.8 million.

As of March 10, 2015, the registrant had 52,827,453 shares of common stock outstanding.

**APPLICABLE ONLY TO REGISTRANTS INVOLVED IN BANKRUPTCY**

**PROCEEDINGS DURING THE PRECEDING FIVE YEARS:**

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes  No

**DOCUMENTS INCORPORATED BY REFERENCE**

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held on May 20, 2015.

## **PART I**

### **Item 1. BUSINESS**

#### **Our Company**

IGI Laboratories, Inc. and subsidiaries (“IGI”, the “Company”) is a specialty generic pharmaceutical company. Our mission is to become a leader in the specialty generic pharmaceutical market. Under our IGI label, we currently 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, or OTC, and cosmetic industries. IGI is a Delaware corporation formed in 1977. Our office, laboratory and manufacturing facilities are located at 105 Lincoln Avenue, Buena, New Jersey 08310.

Currently, we have two platforms for growth:

Developing, manufacturing and marketing a portfolio of generic pharmaceutical products under our own label in topical, injectable, complex and ophthalmic dosage forms; and,

Managing our current contract manufacturing and formulation services business.

We currently operate and generate revenue in one segment, which includes the manufacture and development of topical pharmaceutical, OTC and cosmetic products. We have been in the contract manufacturing and development of topical products business since the early 1990s, but our strategy since 2010 has been focused on the growth of our own generic pharmaceutical business. In 2014, we focused on the transformation of our business that was working toward being a leader in the topical generic pharmaceutical industry into becoming a leader in the broader specialty generic pharmaceutical markets. We believe that expanding our development and commercial base beyond topical generics, historically the cornerstone of our expertise, to include injectable generics, complex generics and ophthalmic generics (what we call our TICO Strategy), will leverage existing expertise and capabilities, and broaden our platform for strategic growth. Currently, we market six products, and we expect to begin marketing an additional product after March 28, 2015. We have recently acquired 21 drug products that have been previously approved by the United States Food and Drug Administration, or the FDA. In our pipeline, we have 22 Abbreviated New Drug Applications, or ANDAs, submitted to the FDA and awaiting approval. We have an additional 45 product candidates in our development pipeline, 15 of which are on stability testing. With the recent completion of the expansion of our research and development laboratories and with modest capital expenditures, we believe that, based on current forecasts, capacity at our existing facility would be sufficient for our topical manufacturing needs into 2017. In 2014, we initiated the planning phase of the expansion of our facility in Buena, New Jersey. Planning will continue in 2015, with the intent that the construction of the expansion will begin toward the end of 2015. In order to manufacture our

sterile injectable and ophthalmic products, we initially intend to partner with contract manufacturing organizations. Over time, we expect to expand our capabilities to include sterile manufacturing by acquiring an existing sterile injectable facility, or by building our own facility. We have evaluated several facilities over the past twelve months while at the same time we continued to pursue options to build our own facility. Based on our findings to date, we anticipate that it is more probable that we will build our own facility with sterile manufacturing capabilities. We plan to make our final decision on the sterile manufacturing facility in the first half of 2015.

In addition, we may continue to explore ways to accelerate our growth through the creation of unique opportunities from the acquisition of additional intellectual property, and the expansion of the use of our existing intellectual property.

### *IGI's Generic Pharmaceutical Business*

In September 2010, we leveraged our existing formulation and manufacturing capabilities to begin IGI's transformation from being solely a contract manufacturing and development company into a generic pharmaceutical company with our own portfolio of products as recognized by our first ANDA submission to the FDA. ANDAs are submitted to the FDA for generic drug products that have the same active ingredient, strength, dosage form, and route of administration as brand name innovator drug products to which they are bioequivalent, meaning that there is no significant difference between the drugs in their rate and extent of absorption in the body. In the United States, approved ANDA generic drugs are usually interchangeable with the innovator drug. This means that the generic version may generally be substituted for the branded product by either a physician or pharmacist when dispensing a prescription. Our commercialization of each of these product candidates requires approval of the respective ANDA by the FDA.

Since September 2010, we have expanded our generic topical pharmaceutical pipeline of prescription products by submitting 24 ANDAs to the FDA. Our goal for the fiscal year 2014 was to submit at least ten additional ANDAs through our internal research and development program and, as of December 31, 2014, we submitted 11 ANDAs.

In December 2012, we launched our first generic topical pharmaceutical products under the IGI label. In March 2014, we received our first approval from the FDA for an ANDA for the generic equivalent of lidocaine hydrochloride USP 4% topical solution. In May 2014, we received tentative approval for our second ANDA, the generic equivalent of diclofenac sodium topical solution 1.5%. We also have a number of additional product candidates in various stages of development. Based on IMS Health Reports data, the addressable market, as of December 2014, for the 22 products we have pending at the FDA totals approximately \$579 million in annual sales. We expect to continue to expand our presence in the generic topical pharmaceutical market through the submission of additional ANDAs to the FDA and the subsequent launch of products if and when these applications are approved by the FDA.

As part of our growth strategy, we also seek opportunities to acquire additional products and ANDAs. On February 1, 2013, we acquired assets and intellectual property, including an approved ANDA, for econazole nitrate cream 1%, which we launched under our label in September 2013. On September 24, 2014, we acquired from AstraZeneca Pharmaceuticals LP previously approved ANDAs and New Drug Applications, or NDAs, associated with 18 products, 17 of which are injectable products and one non-injectable product for pain management. On September 30, 2014, we acquired previously marketed and approved ANDAs and NDAs associated with two ophthalmic products from Valeant Pharmaceuticals LLC and Valeant Pharmaceuticals Luxembourg SARL, or Valeant, in addition to the exclusive right to acquire three additional previously marketed and approved injectable products from Valeant. In

November 2014, we completed the purchase of one of those three optioned injectable products and its related NDA from Valeant.

In addition, as part of our development expansion program, we have started two 505(b)(2) new drug application projects and also plan to include products in our pipeline that will require clinical end point studies to demonstrate bioequivalence. A 505(b)(2) submission is an NDA that contains full safety and effectiveness reports, but permits some of the information required for approval to come from studies not conducted by or for the applicant, thereby avoiding unnecessary duplication of studies already performed on a product.

#### *Contract Manufacturing and Development Business*

We also develop, manufacture, fill and package topical semi-solid and liquid products for branded and generic pharmaceutical customers, as well as the OTC and cosmetic industries. These products are used in a wide range of applications, from purely cosmetic to the prescription treatment of conditions like dermatitis, psoriasis and eczema.

Our contract manufacturing and development business includes two services: contract formulation and contract manufacturing. These services are offered to pharmaceutical, OTC and cosmetic customers. For our pharmaceutical contract services customers, we formulate, test and/or manufacture prescription drugs and medical devices. The products include cosmetics sold by retail stores directly to the public, as well as prescription drug products promoted directly to physicians. All contract manufacturing products are produced under our customers' labels. As a result of our commitment to file at least 20 topical ANDAs for the IGI portfolio in 2015, our research and development team will be focused more on the growth of our organic pipeline. Therefore, we do not expect to record significant revenues from our contract formulation services in 2015 and beyond.

Contract development involves developing topical formulations to satisfy a customer's product request. Our experienced formulators can develop a novel formulation or replicate an existing formula through reverse engineering. We offer full support for the products we develop through developing test methods, full analytical services, manufacturing scale-up criteria, validation and regulatory assistance. Upon completion of our contract formulation projects, we are often successful in securing contract manufacturing services to manufacture the products we helped the customer develop. We have filed several 510(k) submissions with the FDA to obtain clearance on behalf of our customers for the marketing and distribution of certain medical devices. In addition, we have four additional ANDAs pending approval at the FDA that we submitted under joint development and commercialization agreements with our partners. In December 2012, after completion of the required formulation and regulatory requirements, we submitted two of those ANDAs on behalf of one of our pharmaceutical partners. In December 2013, we submitted another of the ANDAs associated with a generic topical pharmaceutical drug product, which, once approved, will be licensed, marketed and distributed by one of our large multi-national pharmaceutical partners, West-Ward Pharmaceuticals Corp. In June 2014, we submitted an ANDA under a joint development and commercialization agreement with Impax Laboratories, Inc.

We believe that our quality contract manufacturing and development business provides a consistent and reliable source of products and services to our customers. We offer flexibility in batch sizing and package design, which gives



our customers the opportunity to select the appropriate presentation for each product. Our high-speed packaging lines can accommodate a variety of tubes, bottles, pumps and jars. As a result of the rollout of our TICO strategy and the increased focus and commitment of R&D and technical resources toward internal projects, we anticipate that revenue from our contract services business will decrease over time.

### *Recent Financings*

On November 18, 2014, we entered into an asset-based revolving senior secured credit facility with General Electric Capital Corporation, or GECC, as agent, and GE Capital Bank and the other lenders party thereto from time to time. Under the credit agreement, we can request revolving loan advances up to an aggregate total amount of \$10,000,000, which may be increased to \$15,000,000 at our request subject to certain conditions, and we may request an incremental facility for revolving loan commitments of up to \$10,000,000. Payment of the amounts financed under the credit agreement is secured by substantially all of our tangible and intangible assets, except intellectual property. We have amended the Credit Agreement to allow for the issuance of our 3.75% Convertible Senior Notes due 2019, or the Notes, which included, among other things, amending the affirmative and negative covenants to permit the issuance of senior indebtedness and to allow for the disposition of assets and permit restricted payments, as may be required pursuant to the terms of the Notes.

On December 10, 2014, we entered into a purchase agreement pursuant to which the Company agreed to sell \$125 million aggregate principal amount of its Notes to Deutsche Bank Securities Inc. and J.P. Morgan Securities LLC, as the initial purchasers. The Notes were sold in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. On December 16, 2014, we completed the sale of the Notes pursuant to the terms of the purchase agreement. In connection with the sale of the Notes, we entered into an indenture by and between the Company and Wilmington Trust, National Association, as trustee, and issued the Notes pursuant thereto. The Notes bear interest at a rate of 3.75% per year, payable semi-annually in arrears on June 15 and December 15 of each year, commencing June 15, 2015. The Notes will mature on December 15, 2019, unless earlier repurchased or redeemed by the Company or converted by holders, pursuant to the terms therein. Additionally, subject to certain conditions, we may redeem for cash any or all outstanding Notes on or after December 19, 2017 in an amount equal to the outstanding principal amount of such Notes, plus accrued and unpaid interest. No sinking fund is provided for the Notes. The Notes are the Company's senior unsecured obligations and will not be guaranteed by any of our existing or future subsidiaries. On December 22, 2014, we announced the closing of the exercise in full by the initial purchasers of their option to purchase an additional \$18.75 million aggregate principal amount of the Notes. Aggregate net proceeds were approximately \$139 million, after deducting underwriter commissions and other expenses paid by us.

### *Corporate Information*

We were incorporated in Delaware in 1977 under the name "IGI, Inc." On May 7, 2008, our stockholders approved our name change from IGI, Inc. to IGI Laboratories, Inc. Our principal executive offices are located at 105 Lincoln Avenue, Buena, New Jersey 08310. Our telephone number is (856) 697-1441. We maintain a website at [www.igilabs.com](http://www.igilabs.com). We make available on or through our website our periodic reports that we file with the Securities and Exchange Commission, or the SEC. This information is available on our website free of charge as soon as reasonably practicable after we electronically file the information with or furnish it to the SEC. The contents of our website are not incorporated by reference into this document and shall not be deemed "filed" under the Securities Exchange Act of 1934, as amended, or the Exchange Act.



## **Our Competitive Strategy**

Our goal is to become a leader in the specialty generic pharmaceutical market. Under our IGI label, we currently sell generic topical pharmaceutical products that are bioequivalent to their brand name counterparts. We also provide development, formulation, and manufacturing services to the pharmaceutical, OTC, and cosmetic industries. We have been in the contract manufacturing and development of topical products business since the early 1990s, but our strategy since 2010 has been focused on the growth of our own generic pharmaceutical business. Since 2010, we have focused on transitioning our business to include more customers in the topical pharmaceutical industry. In 2014, we started the transformation of our business from working toward being a leader in the topical generic pharmaceutical industry to becoming a leader in the specialty pharmaceutical markets. We believe that expanding our development and commercial base beyond topical generics, the cornerstone of our expertise, to injectable generics, complex generics and ophthalmic generics (what we call our TICO Strategy), will leverage existing expertise and capabilities, diversify our commercial opportunities and broaden our platform for long-term strategic growth.

### *Our TICO Strategy*

Our TICO Strategy originated from our opportunity to leverage the industry value chain, which we have developed and strengthened through our topical portfolio. This value chain includes our internal expertise in product and molecule selection and development, manufacturing, sales, logistics and distribution, as well as our relationships with our customers and consumers. With the notable exception of manufacturing capabilities, we see the potential to effectively leverage our existing infrastructure across this value chain and to further expand our strategic reach to the injectable, complex and ophthalmic generic pharmaceutical markets.

*Topical (T)* - Our focus on the topical market has been the foundation for our growth. While the company has manufactured topical products since the early 1990s, we began to focus our strategy on the topical generic market in 2010. In December 2012, we launched our first generic topical pharmaceutical products under the IGI label. In March 2014, we received our first approval from the FDA for an ANDA for the generic equivalent of lidocaine hydrochloride USP 4% topical solution. In May 2014, we received tentative approval for our second ANDA, the generic equivalent of diclofenac sodium topical solution 1.5%. Currently, we market six products, and we expect to begin marketing an additional product after March 28, 2015. In our topical pipeline, we have 22 ANDAs submitted to the FDA that are awaiting approval, and an additional 45 product candidates in our development pipeline, 15 of which are on stability testing. We intend to continue to develop topical generic products and utilize our expertise in drug formulation and manufacture to expand our own generic topical prescription drug portfolio. We are targeting to develop and file regulatory submissions with the FDA at least twenty topical products in 2015 through the ANDA process. Upon regulatory approval, we would then market these products under the IGI label to national chain drug stores and drug wholesalers through our internal sales efforts. Based on IMS Health Reports data, the addressable market, as of December 2014, for the 22 products we have pending at the FDA totals approximately \$579 million in annual sales.

In our topical contract services business, we have developed strong customer relationships that we believe provide us with both recurring revenue streams from those customers and opportunities to selectively increase our product offerings to our customers. We intend to continue to capitalize on our strong customer relationships to maintain some contract manufacturing and development revenues.

We have an FDA-registered, cGMP-compliant facility that is equipped for manufacturing topical, semi-solid and liquid products. The design and configuration of our manufacturing facility provides flexibility in manufacturing batch sizes from 250 kg up to 4,000 kg. We intend to leverage this flexibility and capacity to support our growth in the topical prescription markets.

*Injectable (I)* - As part of the injectable phase of our TICO Strategy, on September 24, 2014, we acquired from AstraZeneca Pharmaceuticals LP previously approved ANDAs and NDAs associated with 18 products, 17 of which are injectable products and one of which is a non-injectable product for pain management. Of the products we acquired, five of the products are currently on the FDA drug shortage list. On September 30, 2014, we acquired previously marketed and approved ANDAs associated with two ophthalmic products from Valeant, in addition to the exclusive right to acquire three additional previously marketed and approved injectable products from Valeant. In November 2014, we completed the purchase of one of those three optioned injectable products and its related NDA from Valeant.

We intend to leverage our existing topical value chain as we build our injectable generic portfolio. In 2015 we are beginning partnerships with contract manufacturing organizations, or CMOs, for the manufacture of our portfolio of sterile products. Longer term, we expect to bring much of this production capability in-house. Since 2014, we have evaluated several opportunities to either acquire assets and infrastructure, which we refer to as our buy option, or to lease and retrofit an existing facility or warehouse, which we refer to as our build option, in order to best execute our long-term TICO Strategy, continue our commitment to high quality, deliver appropriate return on capital and ensure production needs that are aligned with our current and future portfolio.

If we proceed with the build option in 2015, we will begin concept, design, equipment ordering and construction activities necessary to qualify a facility for both pilot- and commercial-scale operations, including an R&D laboratory, sterile manufacturing and packaging capabilities, and warehouse and administrative space.

We plan to continue to review business development opportunities to expand our injectable portfolio.

*Complex (C)* – We have recently begun two projects that we consider to be part of the complex portfolio of our TICO Strategy. We consider our focus on complex products or markets to be broadly defined to include potential complexity in one of the critical areas of our industry value chain. As part of our complex program, we have started two 505(b)(2) projects. A 505(b)(2) submission is an NDA that contains full safety and effectiveness reports, but permits some of the information required for approval to come from studies not conducted by or for the applicant, thereby avoiding unnecessary duplication of studies already performed on a product. We will continue to seek opportunities relevant to building our complex portfolio of products.

*Ophthalmic (O)* - As part of the ophthalmic portfolio of our TICO Strategy, on September 30, 2014, we acquired previously marketed and approved ANDAs associated with two ophthalmic products from Valeant. Similar to our injectable portfolio, we are forming partnerships with CMOs for near-term commercial production, but plan to eventually manufacture these products within our own facility. We plan to continue to review business development opportunities to expand our ophthalmic portfolio.

## **Our Customers**

The manufacturing and commercialization of generic specialty pharmaceutical markets is competitive, and there are established manufacturers, suppliers and distributors actively engaged in all phases of our business. We currently only manufacture and sell topical generic pharmaceutical products under our own label. As we continue to execute our TICO strategy, we will compete in other markets, including the injectable and ophthalmic generic pharmaceutical markets, and expect to face other competitors.

In 2014, 31% of our total product sales, net were to one of the three large wholesale drug distributors noted below. The three large wholesale drug distributors are: AmerisourceBergen Corporation, or ABC, Cardinal Health, Inc., or Cardinal, and McKesson Drug Company, or McKesson.

ABC accounted for approximately 30% of our accounts receivable as of December 31, 2014. None of our IGI label customers accounted for more than 10% of total revenue or accounts receivable in 2013 and 2012.

ABC, Cardinal and McKesson are key distributors of our products, as well as a broad range of health care products for many other companies. None of these distributors is an end user of our products. Generally speaking, if sales to any one of these distributors were to diminish or cease, we believe that the end users of our products would likely find little difficulty obtaining our products either directly from us or from another distributor. However, the loss of one or more of these distributors, together with a delay or inability to secure an alternative distribution source for end users, could have a material negative impact on our revenue, business, financial condition and results of operations. Furthermore, AmerisourceBergen, Cardinal and McKesson have recently entered into strategic alliances with Walgreens, CVS Caremark and Rite-Aid, respectively. Since Walgreens, CVS Caremark and Rite-Aid are customers for several of our products, the loss of our distributor relationship with any of the three large wholesalers could result in a reduction to our revenues.

We consider our business relationships with ABC, Cardinal and McKesson to be in good standing and have fee for services contracts with each of them. However, a change in purchasing patterns, a decrease in inventory levels, an increase in returns of our products, delays in purchasing products and delays in payment for products by one or more of these distributors could have a material negative impact on our revenue, business, financial condition and results of operations.

Our customers in the contract manufacturing business generally consist of pharmaceutical companies, as well as cosmetic and OTC product marketers, who require product development/manufacturing support. In 2014, approximately 79% of our revenue was derived from pharmaceutical customers, as compared to 61% of total contract manufacturing revenue in 2013. One of our contract manufacturing services customers represented 13% of total revenue in 2014. We do not expect any contract manufacturing or formulation services customers to exceed 10% of revenue in 2015 and beyond.



## Our Products

Below is a listing of our products that have been launched (or are expected to be launched), along with a description of each respective formulation, presentation, launch date, and indication.

<b>Product</b>	<b>Formulation</b>	<b>Presentations</b>	<b>Launch date</b>	<b>Indication</b>
Fluocinolone acetonide 0.01% <sup>(a)</sup>	Solution	60mL	December 2012	Indicated for the relief of the inflammatory pruritic manifestations of corticosteroid-responsive dermatoses
Fluocinolone acetonide 0.025% <sup>(a)</sup>	Ointment	15g, 60g	January 2013	Indicated for the relief of the inflammatory pruritic manifestations of corticosteroid-responsive dermatoses
Fluocinolone acetonide 0.025% <sup>(a)</sup>	Cream	15g, 60g	January 2013	Indicated for the relief of the inflammatory pruritic manifestations of corticosteroid-responsive dermatoses
Fluocinolone acetonide 0.01% <sup>(a)</sup>	Cream	15g, 60g	April 2014	Indicated for the relief of the inflammatory pruritic manifestations of corticosteroid-responsive dermatoses
Econazole nitrate 1%	Cream	15g, 30g, 85g	September 2013	Indicated for the treatment of tinea pedis, tinea cruris, and tinea corporis as well as the treatment of cutaneous candidiasis and tinea versicolor
Lidocaine hydrochloride 4%	Solution	50mL	May 2014	Indicated for the production of topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestion tract
Diclofenac sodium 1.5%	Solution	150mL	Expected Spring 2015	Indicated for the treatment of osteoarthritis pain in the knee

Below is a listing of the previously marketed products that were purchased from AstraZeneca and Valeant, along with a description of each respective formulation, presentation, brand equivalent, dossier and indication.

<b>Product</b>	<b>Formulation</b>	<b>Presentations</b>	<b>Brand equivalent</b>	<b>Dossier type held by IGI</b>	<b>Overview</b>
Ciprofloxacin 0.3%	Ophthalmic Solution	2.5ml, 5ml, 10ml bottles	Ciloxan ®	ANDA	Indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of various microorganisms.
Betaxolol 0.5%	Ophthalmic Solution	5ml, 7.5ml, 15ml bottles	Betopic ®	ANDA	Indicated for lowering intraocular pressure and is indicated in the treatment of ocular hypertension and chronic open-angle glaucoma.
Phytonadione 10mg/ml, 1mg/0.5ml	Injectable	0.5ml, 1ml ampoules; 3cc, 6cc vials	AquaMephyton ®	NDA	Indicated for the treatment of vitamin K deficiency and to treat certain bleeding or blood clotting problems.
Amikacin Sulfate 50mg/ml and 250mg/ml	Injectable	2ml, 4ml vials	Amikacin Sulfate ®	ANDA	Indicated for the short-term treatment of serious infections due to susceptible strains of gram-negative bacteria.
Calcitonin Salmon 200IU/ml	Injectable	2ml vials	Miacalcin ®	ANDA	Indicated for the treatment of symptomatic Paget's disease of bone in patients with moderate to severe disease characterized by polyostotic involvement with elevated serum alkaline phosphatase and urinary hydroxyproline excretion.
Cefotetan Disodium	Injectable (vial)	1gr, 2gr, 10gr vials	Cefotetan ®	NDA / ANDA	Indicated for the treatment of various bacterial infections.
Cefotetan Disodium 20mg/ml	Injectable (bag)	50ml bags	Cefotetan ®	NDA	Indicated for the treatment of various bacterial infections.
Clindamycin Phosphate 150mg/ml	Injectable	2ml, 4ml, 6ml, 60ml vials	Cleocin ®	ANDA	Indicated for the treatment of serious infections caused by susceptible anaerobic bacteria.
Dobutamine HCl 12.5mg/ml	Injectable	20ml, 40ml vials	Dobutamine HCl ®	ANDA	Indicated when parenteral therapy is necessary for inotropic support in the short-term treatment of adults with cardiac decompensation due to depressed contractility resulting either from organic heart disease or from cardiac surgical procedures
Dopamine HCl 40mg/ml	Injectable	5ml, 10ml (vials and syringes)	Dopamine HCl ®	NDA / ANDA	Indicated for the correction of hemodynamic imbalances present in the shock syndrome due to myocardial infarction, trauma, endotoxic septicemia, open-heart surgery,

Dopamine HCl 80mg/ml	Injectable	5ml, 10ml (vials, ampoules, and syringes)	Dopamine HCl ®	NDA / ANDA	renal failure, and chronic cardiac decompensation as in congestive failure. Indicated for the correction of hemodynamic imbalances present in the shock syndrome due to myocardial infarction, trauma, endotoxic septicemia, open-heart surgery, renal failure, and chronic cardiac decompensation as in congestive failure.
Dopamine HCl 160mg/ml	Injectable	5ml (vials and ampoules)	Dopamine HCl ®	NDA / ANDA	Indicated for the correction of hemodynamic imbalances present in the shock syndrome due to myocardial infarction, trauma, endotoxic septicemia, open-heart surgery, renal failure, and chronic cardiac decompensation as in congestive failure.
Droperidol 2.5mg/ml	Injectable	10ml vials, 2ml and 5ml ampoules, and 2ml syringes	Inapsine ®	ANDA	Indicated to reduce the incidence of nausea and vomiting associated with surgical and diagnostic procedures.
Furosemide 10mg/ml	Injectable	2ml, 4ml, 8ml, and 10ml vials, 4ml and 10ml syringes	Furosemide ®	ANDA	Indicated in adults and pediatric patients for the treatment of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including the nephrotic syndrome. Furosemide is particularly useful when an agent with greater diuretic potential is desired.
Mannitol USP 25%	Injectable	50ml (vials and syringes)	Mannitol ®	ANDA	Furosemide is also indicated as adjunctive therapy in acute pulmonary edema. The intravenous administration of furosemide is indicated when a rapid onset of diuresis is desired, e.g., in acute pulmonary edema. Indicated for the following purposes in adults and pediatric patients: 1) promotion of diuresis in the prevention or treatment of the oliguric phase of acute renal failure before irreversible renal failure becomes established, 2) reduction of intracranial pressure and brain mass, 3) reduction of high intraocular pressure when the pressure cannot be lowered by other means, 4) promotion of urinary excretion of toxic materials.
Meperidine HCl 20mg/ml, 25mg/ml, 50mg/ml, 75mg/ml, 100mg/ml	Injectable	1ml and 30ml vials, 1ml and 1.5ml ampoules, and 1ml syringes	Demerol ®	ANDA	Indicated for the relief of moderate to severe pain.
Midazolam HCl 5mg/ml	Injectable	2ml syringe	Midazolam ®	ANDA	Indicated for preoperative sedation/anxiolysis/amnesia



<b>Product</b>	<b>Formulation</b>	<b>Presentations</b>	<b>Brand equivalent</b>	<b>Dossier type held by IGI</b>	<b>Overview</b>
Nalbuphine HCl 10mg/ml, 20mg/ml	Injectable	1ml ampoules, 1ml and 10ml vials, and 1ml syringes	Nalbuphine ®	ANDA	Indicated for the relief of moderate to severe pain. Nalbuphine hydrochloride can also be used as a supplement to balanced anesthesia, for preoperative and postoperative analgesia, and for obstetrical analgesia during labor and delivery.
Naloxone HCl 0.4mg/ml, 1mg/ml	Injectable	1ml, 2ml, 5ml, 10ml (vials, ampoules, or syringes)	Naloxone ®	ANDA	Indicated for the complete or partial reversal of narcotic depression, including respiratory depression, induced by opioids including natural and synthetic narcotics, propoxyphene, methadone and certain narcotic-antagonist analgesics: nalbuphine, pentazocine and butorphanol. Naloxone hydrochloride is also indicated for the diagnosis of suspected acute opioid overdose.
Pancuronium Bromide 1mg/ml, 2mg/ml	Injectable	10ml vials, 2ml and 5ml (vials, ampoules, and syringes)	Pancuronium ®	ANDA	Indicated as an adjunct to general anesthesia to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation.
Tobramycin Sulfate 10mg/ml, 40mg/ml	Injectable	2ml and 30ml vials, 1.5ml and 2ml syringes	Tobramycin ®	ANDA	Indicated for the treatment of serious bacterial infections caused by susceptible strains of designated microorganisms.
MVI-12	Injectable	Lyo vials	MVI-12 ®	NDA	Indicated for the prevention of vitamin deficiency in adults and children aged 11 years and above on warfarin anticoagulant therapy receiving parenteral nutrition.
Lidocaine Suppository	Suppository	100mg	Xylocaine ®	NDA	

## Our Suppliers

We require a supply of quality raw materials and components to manufacture and package pharmaceutical products for ourselves and third parties with which we have contracted. The principal components of our products are active and inactive pharmaceutical ingredients and certain packaging materials. Many of these components are available from only a single source and, in the case of many of our ANDAs, only one supplier of raw materials has been identified. Because FDA approval of drugs requires manufacturers to specify their proposed suppliers of active ingredients and certain packaging materials in their applications, FDA approval of any new supplier would be required if active ingredients or such packaging materials were no longer available from the specified supplier. The qualification of a new supplier could delay our development and marketing efforts. If for any reason we are unable to

obtain sufficient quantities of any of the raw materials or components required to produce and package our products, we may not be able to manufacture our products as planned. In addition, certain of the pharmaceutical products that we market are manufactured by third parties that serve as our only supplier of those products. Any delays or failure of a contract manufacturing partner to supply finished goods timely or in adequate volume could impede our marketing of those products. No supplier represented 10% or more of our purchases in 2014, 2013 or 2012.

## **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 fourteen full-time employees and their responsibilities include: formulation, reverse engineering, methods development, analytical and microbiologic testing and scale up, and regulatory expertise. Our employees have specific expertise in developing topical products in a wide range of dosage forms, including simple solutions through complex creams. All ANDA development is conducted in-house except for bioequivalence testing, which is performed by what we believe to be a qualified contract research organization.

We have been steadily increasing our investment in R&D as we believe that R&D is the future of IGI. We incurred \$6.9, \$2.7 and \$2.8 million on R&D expenses in 2014, 2013 and 2012, respectively. We expect to increase our R&D spending in 2015 to approximately 27% to 28% of revenue in 2015 to expand our ANDA submissions and pipeline.

## **Sales and Marketing**

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

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

## **Competition**

In our generic topical prescription drug business, we face competition in the topical generic drug market from other generic drug manufacturers and brand-name pharmaceutical companies through authorized generics. Although there are a significant number of competitors in the generic drug market, there are fewer competitors in the topical generic drug market. The six dominant companies in the topical generic drug market consist of Taro Pharmaceutical Industries, Ltd., Sandoz, (the generic pharmaceutical division of Novartis AG), Actavis, Inc., Perrigo Company, Mylan, Inc. and Akorn, Inc.. Collectively, these six competitors control approximately 68% of the generic topical market by value based on IMS data in January 2015. We believe the concentrated nature of the topical generic drug market creates an opportunity for us in that we believe we will be able to compete based on a variety of factors, including our focus on niche opportunities within the market segment and our dedication to quality in every area of our business.

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

will continue to service our existing customers in this market by providing high quality, customer-oriented service, complemented by our contract development expertise in topical formulations.



## **Environmental Matters**

Our operations are subject to a variety of environmental, health and safety laws and regulations, including those of the United States Environmental Protection Agency and equivalent state and local regulatory agencies. These laws and regulations govern, among other things, air emissions, wastewater discharges, the use, handling and disposal of hazardous substances and wastes, soil and groundwater contamination and employee health and safety. Our manufacturing facility uses, in varying degrees, hazardous substances in its processes. Contamination at our facility can result and has resulted in liability to us, for which we have recorded appropriate reserves as needed. For example, two of the Company's facilities have undergone remediation of environmental contamination. See Note 16 to the Company's Consolidated Financial Statements included elsewhere in this Annual Report.

## **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 continue to rely in the future, 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 us 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 an approximately 23,000 square foot facility built on 7.3 acres of land in 1995, which we own. This facility is used for production, product development, marketing and warehousing for our pharmaceutical, cosmeceutical and cosmetic products. Our manufacturing capabilities encompass a full suite of competencies, including regulatory, quality assurance and in-house validation.

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

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

## **Employees**

On December 31, 2014, we had a total of 81 full-time employees. In addition, as the need arises, we occasionally utilize short-term, part-time employees who are paid on an hourly basis. In addition, we utilize temporary employees provided by a third-party on a regular basis, primarily in our production department. We do not have a collective bargaining agreement with our employees and we believe that our employee relations are good.

## **Item 1A. RISK FACTORS**

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

### **Risks Related to Our Business**

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

Prior to 2014, our expenses have exceeded our revenue in each of the last nine years, and no net income has been available to common stockholders during each of these years. As of December 31, 2014, our stockholders' equity was \$39.1 million and we had an accumulated deficit of \$39.6 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 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. Two of our customers accounted for 67% of our revenue for the three months ended December 31, 2014, and three of our customers accounted for 30% of our revenue for the three months ended December 31, 2013. Two of our customers accounted for 44% of our revenue for the twelve months ended December 31, 2014, and three of our customers accounted for 39% of our revenue for the twelve months ended December 31, 2013. 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 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.

**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 that 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 may decline potentially 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, may 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.

**If pharmaceutical companies are successful in limiting the use of generics through their legislative, regulatory and other efforts, sales of our generic products may be adversely impacted.**

Many pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

pursuing new patents for existing products that may be granted just before the expiration of earlier patents, which could extend patent protection for additional years or otherwise delay the launch of generics;

selling the brand product as an authorized generic, either by the brand company directly, through an affiliate or by a marketing partner;

using the Citizen Petition process to request amendments to FDA standards or otherwise delay generic drug approvals;

- seeking changes to the U.S. Pharmacopeia, an FDA- and industry-recognized compendia of drug standards;

- attaching patent extension amendments to non-related federal legislation;

engaging in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs, which could have an impact on products that we are developing; and

- seeking patents on methods of manufacturing certain active pharmaceutical ingredients.

If pharmaceutical companies or other third parties are successful in limiting the use of generic products through these or other means, our sales of our generic products may decline. If we experience a material decline in generic product sales, our results of operations, financial condition and cash flows may be significantly and adversely impacted.

**Our generics business also faces increasing competition from brand-name manufacturers that do not face any significant regulatory approval or other barriers to enter into the generics market.**

Our generics business also faces increasing competition from brand-name manufacturers that do not face any significant regulatory approval or other barriers to enter into the generics market. These brand-name companies sell generic versions of their products to the market directly, acquire or form strategic alliances with our competitor generic pharmaceutical companies, or grant them rights to sell “authorized generics.” Moreover, brand-name companies continually seek new ways to delay the introduction of generic products and decrease the impact of generic competition, such as filing new patents on drugs whose original patent protection is about to expire, developing patented controlled-release products, changing product claims and product labeling, or developing and marketing as over-the-counter products those branded products that are about to face generic competition. Our competitors, which include major multinational corporations, are consolidating, and the strength of the combined companies could affect our competitive position in all of our business areas. Furthermore, if one of our competitors or its customers acquires any of our customers or suppliers, we may lose business from the customer or lose a supplier of a critical raw material.

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

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



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

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

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

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

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

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

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

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

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

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

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

Our operations and properties are also subject to a wide variety of increasingly complex and stringent federal, state and local environmental laws and regulations, including those governing the remediation of contaminated soil and groundwater. Such environmental laws may apply to conditions at properties and facilities presently or formerly owned or operated by us, as well as to conditions at properties at which wastes or other contamination attributable to us have been sent or otherwise come to be located. One of our facilities has undergone remediation of environmental contamination, and one of our facilities is currently undergoing remediation of environmental contamination. The total estimated costs for the clean-up and remediation is \$836,000 as of December 31, 2014, and remaining costs accrued at

December 31, 2014 totaled \$80,000. 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 by the FDA and other federal, state and local regulatory authorities 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, among other things, are 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 our 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 Convention, or USP, a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the FDA.

The FDA regulates the testing, manufacture, labeling, marketing and sale of pharmaceutical products. Approval by the FDA is required before any new drug, including any new generic 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 ANDA route, which requires us to demonstrate to the FDA that each generic product candidate has the same active ingredient, strength, dosage form, route of administration and intended use as a corresponding approved drug product and is bioequivalent to the branded drug product, meaning that there is no significant difference between the drugs in their rate and extent of absorption in the body. 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 data or information, which could delay approval of the product and impair our ability to compete with the brand-name drug product and/or other generic versions of the product.

If our product candidates receive FDA approval through the ANDA process, the labeling claims and marketing statements that we can make for our generic drugs are generally limited to the claims approved by the FDA for use 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, 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 pharmaceutical cGMPs or other applicable requirements identified during such inspections may result in recalls or other enforcement actions, including warning letters, 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 suspension or withdrawal of marketing approvals, seizures or recalls of products from the market, or civil or criminal fines or penalties, any of which could significantly and adversely affect supplies of our products.



**During our efforts to expand our existing manufacturing facility, as well as potentially select and build out an additional manufacturing facility, we could experience business interruptions, as well as incur significant capital expenditures to complete the expansions, which may have a material adverse effect on our business, financial position and results of operations.**

We manufacture drug products at one domestic manufacturing facility. This facility may be forced to shut down or may be unable to operate at full capacity as a result of potential expansion plans. In addition, we are in the process of potentially selecting a second manufacturing facility, where we could experience the same risks. A significant disruption at this facility, or potentially a second facility, even on a short-term basis, could impair our ability to produce and ship drug products to the market on a timely basis, which may have a material adverse effect on our business, financial position and results of operations.

**We could experience business interruptions at our manufacturing facility, which may have a material adverse effect on our business, financial position and results of operations.**

We manufacture drug products at one domestic manufacturing facility. This facility may be forced to shut down or may be unable to operate at full capacity as a result of hurricanes, tornadoes, earthquakes, storms and other extreme weather events as well as strikes, war, violent upheavals, terrorist acts and other force majeure events. A significant disruption at this facility, even on a short-term basis, could impair our ability to produce and ship drug products to the market on a timely basis, which may have a material adverse effect on our business, financial position and results of operations.

**Our reporting and payment obligations related to our participation in federal health care programs, including Medicare and Medicaid, are complex and often involve subjective decisions that could change. Any failure to comply with those obligations could subject us to investigation, penalties, and sanctions.**

Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal health care programs, including Medicare and Medicaid, are complex. These programs generally require us to pay rebates or provide discounts to government payors in connection with our products that are dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the government agencies that administer the programs. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in changes that may have material adverse legal, regulatory, or economic consequences. Responding to current and future changes may increase our costs and the complexity of compliance will be time-consuming, and could have a material adverse effect on our results of operations.

In addition, the Office of Inspector General has recently increased its focus on the methodologies used by manufacturers to calculate the average manufacturer price, or AMP, and best price, or BP, to assess manufacturer compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for overcharging government payors. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in a civil monetary penalty of \$10,000 per day for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations.

**We are subject to federal and state healthcare fraud and abuse and false claims laws and may be subject to related litigation brought by the government or private individuals.**

We are subject to state and federal healthcare laws pertaining to fraud and abuse, physician payment transparency and laws that govern the submission of claims for reimbursement. These laws include the following:

the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as Medicare and Medicaid. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;



the federal False Claims Act, or FCA, which 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. The FCA also allows private individuals to bring a suit on behalf of the government against an individual or entity for violations of the FCA. These suits, also known as qui tam actions, may be brought by, with only a few exceptions, any private citizen who believes that he has material information of a false claim that has not yet been previously disclosed. These suits have increased significantly in recent years because the FCA 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;

federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters;

the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other "transfers of value" to such physician owners and their immediate family members;

the Federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

analogous state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our past or present operations are found to be in violation of any of such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal health care programs, and/or the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, or restructuring of our operations could adversely affect our ability to operate our business and our financial results, action against us for violation of these laws, even if we successfully defend against them, it could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.



**Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.**

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures.

**Even after our products receive regulatory approval, such products may not achieve expected levels of market acceptance.**

Even if we are able to obtain regulatory approvals for our generic pharmaceutical products the success of those products is dependent upon market acceptance. Levels of market acceptance for our products could be impacted by several factors, including but not limited to:

- the availability of alternative products from our competitors;
- the price of our products relative to that of our competitors;
- the timing of our market entry;
- the ability to market our products effectively to the different levels in the distribution chain;
- other competitor actions; and
- the continued acceptance of and/or reimbursement for our products by government and private formularies and/or third party payors.

Additionally, studies of the proper utilization, safety, and efficacy of pharmaceutical products are being conducted by the industry, government agencies, and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety, and efficacy of previously marketed as well as future products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs, such as the need for a patient registry, as well as delays in approvals. The occurrence of any of the above risks could adversely affect our profitability, business, financial position, results of operations and/or cash flow, and could cause the market value of our common stock to decline.

**Product recalls could harm our business.**

Product recalls or product field alerts may be issued at our discretion or required by 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 or other quality issues. 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 other 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.

**Counterfeit versions of our products could harm our patients and reputation.**

Our industry has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous manufacturing and

testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the active pharmaceutical ingredient, or API, or no API at all. However, to distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as ours. Additionally, it is possible that adverse events caused by unsafe counterfeit products would mistakenly be attributed to the authentic product. In addition, there could be thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels. Public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

**The testing required for the regulatory approval of our products is conducted by independent third parties. Any failure by any of these third parties to perform this testing properly and in a timely manner may have an adverse effect upon our ability to obtain regulatory approvals.**

Our applications for the regulatory approval of our products incorporate the results of testing and other information that is conducted or gathered by independent third parties (including, for example, manufacturers of raw materials, testing laboratories, contract research organizations or independent research facilities). Our ability to obtain regulatory approval of the products being tested is dependent upon the quality of the work performed by these third parties, the quality of the third parties' facilities, and the accuracy of the information provided by third parties. We have little or no control over any of these factors. If this testing is not performed properly, our ability to obtain regulatory approvals could be restricted or delayed.

**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 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 they are published or the patent is issued, 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 resolutions, 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 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.

**We may not be able to fully realize the expected benefits from the acquisition of certain products.**

Our recent acquisition of certain products subjects us to additional operational and financial risks, including the following:

- additional costs that we may need to incur in order to return the products to the market and to comply with regulatory requirements;

- difficulties in coordinating research and development activities;

- uncertainties in the business relationships with our customers and suppliers; and

- lack of previous experiences in manufacturing, commercializing, and distributing products in therapeutic areas outside of the topical generic pharmaceutical market.

**Our approved products may not achieve commercialization at levels of market acceptance that allow us to achieve profitability, which could have a material adverse effect on our business, financial position and results of operations.**

We seek to develop, license or acquire products that we can commercialize at levels of market acceptance that would allow us to recoup the costs of development and commercialization, grow market share, and achieve profitability. Even if we are able to obtain regulatory approvals for certain pharmaceutical products, if we fail to accurately predict demand for such products, our business, financial position, and results of operations could be adversely impacted. Levels of market acceptance for products could be impacted by several factors, including but not limited to:

- the availability of alternative products from our competitors;
- the price of our products relative to that of our competitors;

- the effectiveness of our marketing relative to that of our competitors;
- the timing of our market entry;
- the ability to market our products effectively to the retail level; and
- the acceptance of our products by government and private formularies.

Some of these factors are not within our control and, if any arises, our profitability, business, financial position and results of operations could be materially adversely affected.

**Future acquisitions and investments could disrupt our business and harm our financial condition and operating results.**

Our growth will depend, in part, on our continued ability to develop, commercialize and expand our drug products, including in response to changing regulatory and competitive pressures. In some circumstances, we accelerate our growth through the acquisition of complementary products and technologies rather than through internal development. The identification of suitable products to be acquired can be difficult, time-consuming and costly, and we may not be able to successfully complete or successfully execute strategies for identified acquisitions. The risks faced in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition and/or product integration challenges;
- coordination of research and development and sales and marketing functions;
- retention of key employees from the acquired company;
- integration of the acquired company's accounting, management information, human resources and other administrative systems;
- the need to implement or improve controls, procedures, and policies at a business that prior to the acquisition may have lacked effective controls, procedures and policies;

liability for activities of the acquired company and/or products before the acquisition, including patent infringement claims, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities;

unanticipated write-offs or charges; and

litigation or other claims in connection with the acquired company or product, including claims from product users, former stockholders or other third parties.

In any acquisition that we may undertake, our failure to address these risks or other problems encountered in connection with any acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities, and harm our business generally.

**We may become involved in legal proceedings from time to time which may result in losses, damage to our business and reputation and place a strain on our internal resources.**

In the ordinary course of our business, we may be involved in legal proceedings with both private parties and certain government agencies, including FDA. Litigation may result in verdicts against us, which may include significant monetary awards, judgments that certain of our intellectual property rights are invalid or unenforceable and injunctions preventing the manufacture, marketing and sale of our products. If disputes are resolved unfavorably, our business, financial condition and results of operations may be adversely affected.

Any litigation, whether or not successful, may damage our reputation. Furthermore, we are likely to incur substantial expense in defending these lawsuits and the time demands of such lawsuits could divert management's attention from ongoing business concerns and interfere with our normal operations.

In the normal course of business, we periodically enter into employment agreements, legal settlements, and other agreements which incorporate indemnification provisions. We maintain insurance coverage which we believe will effectively mitigate our obligations under these indemnification provisions. However, should our obligation under an indemnification provision exceed our coverage or should coverage be denied, it could have a material adverse effect on our business, financial position and results of operations.

**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.

**Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited.**

As of December 31, 2014, we had federal net operating loss carry forwards (NOLs) of approximately \$26.6 million which expire from 2020 through 2032. Our ability to utilize our NOLs may be limited under Section 382 of the Internal Revenue Code. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). Our ability to use net operating loss carry forwards is subject to substantial limitation in future periods under certain provisions of Section 382 of the Internal Revenue Code, which limit the utilization of net operating losses upon a more than 50% change in ownership of our stock that is held by 5% or greater stockholders. We examined the application of Section 382 with respect to an ownership change that took place during 2010, as well as the limitation on the application of net operating loss carry forwards. We believe that operating losses subsequent to the change date in 2010 (aggregating \$8.5 million) are not subject to Section 382 limitations. We have estimated that the annual limitation starting in 2010 aggregates from \$1.0 million to \$2.3 million per year including the effect of amortization of built in gains.

### **Risks Related to Our Common Stock**

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

For the twelve months ended December 31, 2014, the average daily trading volume of common stock on the NYSE MKT was approximately 599,000 shares. As a result of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.



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

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

**If we fail to comply with the reporting obligations of the 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, 2014 and December 31, 2013, and our management concluded that our disclosure controls and procedures were effective as of such times. The year ended December 31, 2014 is the first year in which we are required to have our external auditors issue an attestation report on the effectiveness of internal controls over financial reporting.

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.

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

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

Our largest stockholders own shares of common stock that have been registered for resale under the Securities Act. The sale of such stock, depending on the interplay of numerous factors, including, without limitation, the method and timing of the sales, could substantially depress the value of 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 \$1.00 in the first quarter of 2013 and a high of \$11.28 in the fourth quarter of 2014. 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;

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

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

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

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

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

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

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

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

**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.

### **Risks Related to the Notes**

**We may not have the ability to raise the funds necessary to settle conversions of the Notes, purchase the Notes as required pursuant to the terms of the indenture governing the Notes or pay the redemption price for any Notes we redeem, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Notes.**

On December 16, 2014, we completed the sale of \$125 million aggregate principal amount of our 3.75% Convertible Senior Notes due 2019 (the "Notes") to Deutsche Bank Securities Inc. and J.P. Morgan Securities LLC as the initial purchasers and on December 22, 2014, we issued to the initial purchasers an additional \$18.75 million aggregate principal amount of the Notes. Pursuant to the terms of the indenture governing the Notes, following certain events, holders of Notes will have the right to require us to purchase their Notes for cash. Such event may also constitute an event of default or prepayment under, and result in the acceleration of the maturity of, our then-existing indebtedness. We cannot assure you that we will have sufficient financial resources, or will be able to arrange financing, to pay the purchase price in cash with respect to any Notes surrendered by holders for purchase at that time, make cash payments upon conversions or pay the redemption price for any Notes we redeem. In addition, restrictions in our then existing credit facilities or other indebtedness, if any, may not allow us to purchase the Notes (even if required pursuant to the terms of the indenture), make cash payments upon conversions of the Notes or pay the redemption price for any Notes

we redeem would result in an event of default with respect to the Notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and purchase the Notes, make cash payments upon conversions thereof or pay the redemption price for any Notes we redeem.



**Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt.**

Our ability to make scheduled payments of the principal of, to pay interest on, to pay any cash due upon conversion of or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

**Until we obtain the necessary stockholder approvals, our ability to settle any conversions of the Notes with shares of our common stock will be limited by certain listing standards of the NYSE MKT and the number of available authorized shares of our common stock.**

Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. However, our ability to settle any conversions with shares of our common stock will be limited by certain listing standards of the NYSE MKT and the number of authorized shares that we have available for such purpose. Accordingly, unless and until we obtain stockholder approval (i) for issuances of our shares of common stock in excess of the NYSE MKT limitations in accordance with its listing standards and/or (ii) for an increase in the number of authorized shares of our common stock, we will settle conversions by paying cash or, subject to certain conditions if we so elect with respect to conversions prior to September 15, 2019, by delivering shares of our common stock.

**To the extent we issue shares of our common stock to satisfy all or a portion of our conversion obligation, conversions of the Notes will dilute the ownership interest of our existing stockholders, including holders who had previously converted their Notes.**

The holders of our Notes can require us, under certain circumstances, to convert their Notes. We have the option to satisfy this conversion obligation with cash, shares of our common stock or a combination of cash and shares of our common stock at our election. To the extent we issue shares of our common stock to satisfy all or a portion of our conversion obligation, the conversion of some or all of the Notes will dilute the ownership interests of our existing stockholders. Any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Notes may encourage short selling by market participants because the conversion of the Notes could depress the price of our common stock.

**Our substantial indebtedness could materially adversely affect our business, financial condition or results of operations and prevent us from fulfilling our obligations under the Notes.**

After giving effect to the issuance of the Notes, we will have a substantial amount of indebtedness. As of December 31, 2014, our total consolidated indebtedness was \$147 million. Our substantial level of indebtedness increases the possibility that we may be unable to generate cash sufficient to pay, when due, the principal of, interest on, or other amounts due in respect of our indebtedness. Our substantial indebtedness, combined with our other financial obligations and contractual commitments, may have a material adverse impact on us. For example, it could

· make it difficult for us to satisfy our obligations with respect to our outstanding and other future debt obligations;

increase our vulnerability to general adverse economic conditions or a downturn in the industries in which we operate;

impair our ability to obtain additional financing in the future for working capital, investments, acquisitions and other general corporate purposes;

require us to dedicate a substantial portion of our cash flows to the payment to our financing sources, thereby reducing the availability of our cash flows to fund working capital, investments, acquisitions and other general corporate purposes; and

place us at a disadvantage compared to our competitors.

**We will continue to have the ability to incur debt; if we incur substantial additional debt, these higher levels of debt may affect our ability to pay the principal of and interest on the Notes.**

We and our subsidiaries may be able to incur substantial additional debt in the future, subject to the restrictions contained in our debt instruments, some of which may be secured debt. The indenture governing the Notes does not restrict our ability to incur additional indebtedness or require us to maintain financial ratios or specified levels of net worth or liquidity. If we incur substantial additional indebtedness in the future, these higher levels of indebtedness may affect our ability to pay the principal of and interest on the Notes, or any fundamental change purchase price or any cash due upon conversion, and our creditworthiness generally.

**The accounting method for convertible debt securities that may be settled in cash, such as the Notes, could have a material effect on our reported financial results.**

Under Accounting Standards Codification 470-20, Debt with Conversion and Other Options, which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. Under ASC 470-20, the equity component is the fair value of variable conversion features. The effect of ASC 470-20 on the accounting for the Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the Notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the Notes to their face amount over the term of the Notes. We will report lower net income in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results, the market price of our common stock and the trading price of the Notes. However, since we do not have enough common shares authorized to issue

upon conversion of the Notes and to comply with certain listing standards of the NYSE MKT upon conversion of the Notes settled in shares of common stock, the conversion feature component will not be recognized as an equity instrument, and instead will be recognized as a derivative liability, which liability will be adjusted to fair value at each reporting period. Changes in the fair value of such liability will be recognized as a component of other income (expense) in the statement of operations. If we receive shareholder approvals authorizing sufficient common shares to allow for the conversion of the debt into shares of common stock and compliance with certain listing standards of the NYSE MKT, the instrument will be adjusted to fair value on the day of such approval, and the balance will be reclassified into the additional paid in capital section of stockholders' equity.

In addition, under certain circumstances, convertible debt instruments (such as the Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the Notes, then our diluted earnings per share would be adversely affected.

#### **Item 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **Item 2. PROPERTIES**

The Company's executive administrative offices are located in Buena, New Jersey, in an approximately 23,000 square foot facility built on 7.3 acres of land in 1995, which we own. This facility is also used for production, product development, marketing and warehousing for our own generic prescription pharmaceutical products and 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. The Company leases an additional 11,000 square feet of warehouse space in Vineland New Jersey, and has recently executed a lease to occupy approximately 10,000 square feet of corporate office space in Iselin, New Jersey.

#### **Item 3. LEGAL PROCEEDINGS**

The Company is not a party to any litigation in any court, and management is not currently aware of any contemplated proceeding by any governmental authority against the Company.

#### **Item 4. MINE SAFETY DISCLOSURES**

Not applicable.



## PART II

Item MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND  
5. ISSUER PURCHASES OF EQUITY SECURITIES

### Performance Graph

Comparison of Cumulative Total Return Among IGI Laboratories, Inc., the S&P 500 Sector Indices - Health Care Sector Index and the Dow Jones - US Healthcare Index

### Market Information

The Company's Common Stock is traded on the NYSE MKT under the symbol "IG." The following table sets forth, for the periods indicated, the high and low sales prices for the Common Stock, as reported by the NYSE MKT.

	Common Stock	
	High	Low
2014:		
First Quarter	6.14	2.93
Second Quarter	6.07	3.84
Third Quarter	9.89	4.94
Fourth Quarter	11.28	7.60
2013:		
First Quarter	1.88	1.00
Second Quarter	2.25	1.32
Third Quarter	2.28	1.24
Fourth Quarter	3.39	1.82

### Stockholders

As of March 10, 2015, there were approximately 435 stockholders of record of the 52,827,453 outstanding shares of Common Stock.



**Dividends**

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

**Unregistered Sales of Securities**

None.

**Issuer Purchases of Equity Securities**

None.

**Item 6. SELECTED FINANCIAL DATA**

The following table sets forth consolidated financial data with respect to the Company for each of the five-year periods ended December 31. The selected financial data for each of the five-year periods ended December 31 have been derived from the consolidated financial statements of the Company, which financial statements have been audited by EisnerAmper LLP, independent registered public accounting firm. The foregoing consolidated financial statements and the report thereon are included elsewhere in this Annual Report on Form 10-K. The information below should be read in conjunction with the consolidated financial statements (and notes thereon) and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included in Item 7.

	As of and For the Years Ended December 31,				
	2014	2013	2012	2011	2010
(In thousands, except per share data)					
Revenues	\$33,740	\$18,224	\$8,563	\$7,806	\$6,094
Gross profit	16,972	6,145	2,776	2,260	1,105
Operating income (loss)	3,906	(82 )	(3,136 )	(2,969 )	(3,631 )
Interest and other non-operating income (expense)	1,518	(199 )	(975 )	(264 )	(9 )
Pretax income (loss)	5,424	(281 )	(4,111 )	(3,233 )	(3,640 )
Income tax provision (benefit)	173	(197 )	(184 )	(226 )	(217 )

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Net income (loss)	\$5,251	\$(84 )	\$(3,927 )	\$(3,007 )	\$(3,423 )
Preferred stock dividend	-	(1,308 )	-	-	(1,284 )
Net income (loss) attributable to common stockholders	\$5,251	\$(1,392 )	(3,927 )	\$(3,007 )	\$(4,707 )
Weighted average shares outstanding:					
Basic	49,818	43,518	39,786	39,449	23,822
Diluted	64,207	43,518	39,786	39,449	23,822
PER SHARE:					
Net income (loss):					
Basic	0.11	(0.03 )	(0.10 )	(0.08 )	(0.20 )
Diluted	0.09	(0.03 )	(0.10 )	(0.08 )	(0.20 )
Share Price: High	11.28	3.39	1.48	1.80	1.90
Low	2.93	1.00	0.94	0.85	0.65
BALANCE SHEET DATA:					
Current assets	\$177,218	\$10,558	\$6,139	\$5,686	\$7,171
Net property, plant & equipment	3,262	2,623	2,691	2,800	2,769
Total assets	197,078	15,427	9,427	9,636	11,351
Current liabilities	13,002	5,221	1,976	1,316	907
Long-term obligations, less current installments	144,942	3,015	1,024	555	97
Shareholders' equity	39,134	7,191	6,427	7,765	10,347
CASH FLOW DATA:					
Cash used in operating activities	\$(3,891 )	\$(618 )	\$(2,373 )	\$(2,394 )	\$(3,013 )
Cash used in investing activities	(3,792 )	(2,113 )	(342 )	(350 )	(195 )
Cash provided by financing activities	164,465	2,296	2,337	542	7,200
Increase/(Decrease) in cash and cash equivalents	156,782	(435 )	(378 )	(2,202 )	3,992

**Item 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

**Forward-Looking Statements**

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

**Company Overview**

*Strategic Overview*

IGI is a specialty generic pharmaceutical company. Our mission is to become a leader in the specialty generic pharmaceutical market. Under our IGI label, we currently 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, or OTC, and cosmetic industries. IGI is a Delaware corporation formed in 1977. Our office, laboratory and manufacturing facilities are located at 105 Lincoln Avenue, Buena, New Jersey 08310.

Currently, we have two platforms for growth:

Developing, manufacturing and marketing a portfolio of generic pharmaceutical products under our own label in topical, injectable, complex and ophthalmic dosage forms; and

Managing our current contract manufacturing and formulation services business.

We currently operate and generate revenue in one segment, which includes the manufacture and development of topical pharmaceutical, OTC and cosmetic products. We have been in the contract manufacturing and development of topical products business since the early 1990s, but our strategy since 2010 has been focused on the growth of our own generic pharmaceutical business. Since 2010, we have focused on transitioning our business to include more customers in the topical pharmaceutical industry. In 2014, we focused on the transformation of a business that was working toward being a leader in the topical generic pharmaceutical industry into becoming a leader in the broader specialty generic pharmaceutical markets. We believe that expanding our development and commercial base beyond topical generics, historically the cornerstone of our expertise, to include injectable generics, complex generics and ophthalmic generics (what we call our TICO Strategy), will leverage existing expertise and capabilities, and broaden our platform for strategic growth. Currently, we market six products, and we expect to begin marketing an additional product after March 28, 2015. We have recently acquired 21 drug products that have been previously approved by the FDA. In our pipeline, we have 22 ANDAs submitted to the FDA and awaiting approval. We have an additional 45 product candidates in our development pipeline, 15 of which are on stability testing.

## Results of Operations

### *Fiscal Year 2014 Compared to Fiscal Year 2013*

We had net income of \$5,251,000 in 2014 compared to a net loss of \$84,000 in 2013. Net income attributable to common stockholders was \$5,251,000, or \$0.11 per basic share in 2014, and net loss applicable to common stockholders was \$1,392,000, or (\$0.03) per share, in 2013:

#### **Revenues (in thousands):**

Components of Revenue:	Year Ended December 31,		Increase/(Decrease)	
	2014	2013	\$	%
Product sales	\$ 32,104	\$ 16,981	\$ 15,123	89 %
Research and development income	1,490	1,094	396	36 %
Licensing, royalty, and other income	146	149	(3 )	(2 )%
Total Revenues	\$ 33,740	\$ 18,224	\$ 15,516	85 %

The increase in product sales for the year ended December 31, 2014 as compared to the same period in 2013 was primarily due to the increased revenue from our own generic pharmaceutical product line that was launched in the first quarter of 2013, the launch of econazole nitrate cream 1% in September 2013 and the launch of two additional IGI label products in June 2014. In addition, we increased product sales in our contract services business to three of our pharmaceutical customers, which was only partially offset by decreased sales to two of our cosmetic 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. Licensing, royalty and other revenue decreased slightly due to a decrease in other revenue, while licensing and royalty revenue remained the same.

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

	Year Ended December 31,		Increase/(Decrease)	
	2014	2013	\$	%
Cost of revenues	\$ 16,948	\$ 12,079	\$ 4,869	40 %
Selling, general and administrative	5,976	3,484	2,492	72 %
Product development and research	6,910	2,743	4,167	152 %
Totals costs and expenditures	\$ 29,834	\$ 18,306	\$ 11,528	63 %

Cost of sales increased for the year ended December 31, 2014 as compared to the same period in 2013 as a result of the increase in total revenue. Cost of sales as a percentage of total revenue was 50% for the year ended December 31, 2014 as compared to 66% for 2013. The decrease in cost of sales as a percentage of product sales for 2014 was

attributable to increased revenue from our IGI label products, which have higher margins, and a shift in the mix of our product sales to include greater higher-margin pharmaceutical products. During 2014, approximately 79% of our revenue from contract and formulation services came from pharmaceutical customers as compared to 61% in 2013. Our research and development income results primarily from services rendered under contractual agreements and, therefore, cost of sales as a percentage of our research and development income is relatively low. Consistent with our strategy, we expect cost of sales as a percentage of total revenue to decline over time.

Selling, general and administrative expenses for the year ended December 31, 2014 increased by \$2,492,000 as compared to the same period in 2013. There were increases in salaries and related costs of \$1,038,000 due to an increase in headcount, professional fees of \$561,000, \$271,000 in expense from the issuance of stock-based compensation related to options and restricted stock, \$255,000 in dues, subscriptions and corporate fees, \$129,000 in recruiting expenses and \$118,000 in travel-related costs during the year ended December 31, 2014 as compared to the same period in 2013. These increases were partially offset by a decrease of \$35,000 in trade show expenses.

Product development and research expenses for the year ended December 31, 2014 increased by \$4,167,000 as compared to the same period in 2013. Consistent with our strategy to expand our portfolio of generic prescription pharmaceutical products, we increased headcount, which resulted in an increase of \$225,000 in salaries and related costs; we increased spending on clinical studies by \$1,122,000, pilot batch expense by \$963,000, outside testing and supplies by \$859,000 and consulting fees by \$299,000. In addition, fees related to the Generic Drug User Fee Act, and the associated filing of our applications with the FDA, increased by \$680,000.

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

	Year Ended December 31,		Increase/(Decrease)	
	2014	2013	\$	%
Interest and other expense, net	\$ (782 )	\$ (199 )	\$ 583	293 %
Change in the fair value of derivative liability	\$ 2,300	\$ -	\$ 2,300	100 %

Interest expense increased for the year ended December 31, 2014 as compared to the same period in 2013, primarily due to the inclusion in 2014 of approximately \$513,000 of interest expense; amortization of debt discount and amortization of debt issuance costs related to the Convertible 3.75% Senior Notes (see Note 6 to the Company's Consolidated Financial Statements). In addition, there was approximately \$42,000 amortization of debt issuance costs related to the payoff of the note payable to Square 1 Bank in 2014 (see Note 8 to the Company's Consolidated Financial Statements). We also recorded a \$2.3 million change in the fair value of the derivative liability as a result in the change in the fair value of our derivative liability, caused primarily by the decrease in the price of our common stock in December 2014.

**Net income (loss):**

	Year Ended December 31,		Increase/(Decrease)	
	2014	2013	\$	%
Net income (loss)	\$ 5,251	\$ (84 )	\$ 5,335	6,351 %

Net income for the year ended December 31, 2014 as compared to net loss for the year ended December 31, 2013 is due to the increase in revenues partially offset by the increase in costs and expenses noted above.

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

	Year Ended December 31,		Increase/(Decrease)	
	2014	2013	\$	%
Net income (loss) attributable to common stockholders	\$ 5,251	\$ (1,392)	) \$ 6,643	477 %
Diluted income (loss) per share	\$ 0.11	\$ (0.03)	) \$ 0.14	467 %

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The net income attributable to common stockholders for the year ended December 31, 2014 as compared to the net loss attributable to common stockholders for the year ended December 31, 2013 is due to the increase in revenues partially offset by the increase in costs and expenses noted above. For the year ended December 31, 2013, there was a preferred stock dividend recorded on December 6, 2013 in connection with the mandatory conversion of our Series C preferred stock. This dividend of \$1,308,000 was recorded upon conversion of our Series C preferred stock into common stock.

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

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

#### **Revenues (in thousands):**

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

The increase in product sales for the year ended December 31, 2013 as compared to the same period in 2012 was primarily due to the launch of our own generic pharmaceutical product line, in addition to increased product sales to five of our pharmaceutical customers and one of our cosmetic customers, which was only partially offset by decreased sales to one of our pharmaceutical customers. Research and development income will not be consistent and will vary, from period to period, depending on the required timeline of each development project. The decrease in research and development income during 2013 as compared to the same period in 2012 is attributable primarily to three new customer relationships with pharmaceutical partners established at the end of 2011 and the beginning of 2012. We completed several site transfers, formulation services, 510(k) submissions for medical devices and filing of two ANDAs for these customers in 2012. In December 2013, we executed a license, development, supply and marketing agreement with a large multi-national pharmaceutical company under which we filed an ANDA in December 2013, and recorded research and development income in accordance with the agreement. Licensing, royalty and other revenue increased slightly due to an increase in other revenue while licensing and royalty revenue remained the same.

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

Cost of revenues	Year Ended December 31,		Increase/(Decrease)	
	2013	2012	\$	%
Cost of revenues	\$ 12,079	\$ 5,787	\$ 6,292	109 %

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Selling, general and administrative	3,484	3,078	406	13	%
Product development and research	2,743	2,834	(91)	(3)	%
Totals costs and expenditures	\$ 18,306	\$ 11,699	\$ 6,607	56	%

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

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

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

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

	Year Ended December 31,		Increase/(Decrease)	
	2013	2012	\$	%
Interest and other expense, net	\$ (199 )	\$ (975 )	\$ (776 )	(80 )%

Interest expense decreased for the year ended December 31, 2013 as compared to the same period in 2012 primarily due to the inclusion in 2012 of approximately \$848,000 of amortization of debt issuance costs related to a note payable to a related party that was paid in full and terminated on August 31, 2012. In addition to the lower interest rate on the note payable to Square 1 (see Note 8 to the Company's Consolidated Financial Statements) that was outstanding for 2013 as compared to the interest rate on the notes payable that were outstanding in the comparable period in 2012, which was partially offset by the increase in note payable in 2013.

We also recorded a tax benefit of \$197,000 in 2013 and \$184,000 in 2012 as a result of a sale of a portion of the Company's state tax operating loss carry forwards to a third party pursuant to a program run by the State of New

Jersey. There can be no assurance that we will continue or be able to continue to sell these operating loss carry forwards.

**Net loss:**

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

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

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

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

The decrease in net loss attributable to common stockholders for the year ended December 31, 2013 as compared to the same period in 2012 is due to the increase in revenues as partially offset by the increase in costs and expenses noted above, which was partially offset by the preferred stock dividend recorded on December 6, 2013, in connection with the mandatory conversion of our Series C preferred stock. This dividend of \$1.3 million was recorded upon conversion of our Series C preferred stock into common stock.

**Liquidity and Capital Resources**

Our principal sources of liquidity are cash and cash equivalents of approximately \$159 million at December 31, 2014, \$6.8 million available under the \$10 million GECC credit facility and cash from operations. We had working capital of \$164 million at December 31, 2014. We may require additional funding and this funding will depend, in part, on the timing and structure of potential business arrangements. If necessary, we may continue to seek to raise additional capital through the sale of our equity or through a strategic alliance with a third party. There may also be additional acquisition and growth opportunities that may require external financing. There can be no assurance that such financing will be available on terms acceptable to us, or at all. We believe that our existing capital resources will be sufficient to support our current business plan beyond March 2016.

On December 10, 2014, we entered into a purchase agreement, pursuant to which we agreed to sell \$125 million aggregate principal amount of our 3.75% Convertible Senior Notes due 2019, or the Notes, to Deutsche Bank Securities Inc. and J.P. Morgan Securities LLC, as the initial purchasers (See Note 21 to the Company's Consolidated Financial Statements). In addition, we granted the initial purchasers a 30-day option to purchase up to an additional \$18.75 million aggregate principal amount of the Notes on the same terms and conditions. The Notes were sold in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended.

On November 18, 2014, we entered into a \$10 million line of credit with GECC (See Note 7 to the Company's Consolidated Financial Statements). As of December 31, 2014, the outstanding principal balance on the line of credit was \$3.2 million.

On June 27, 2014, we announced the pricing of our underwritten public offering of 4,650,000 shares of our common stock at a price to the public of \$5.00 per share (See Note 19 to the Company's Consolidated Financial Statements). The offering closed on July 2, 2014, and, after giving effect to the underwriters' exercise of the over-allotment option in full, we sold an aggregate of 5,347,500 shares of common stock. The net proceeds of the offering were approximately \$24.9 million, after deducting the underwriters' commission and offering expenses.

Our operating activities used \$3.9 million, \$0.6 million and \$2.4 million of cash during the years ended December 31, 2014, 2013 and 2012, respectively. The use of cash for the year ended December 31, 2014 was substantially a result of the changes in operating assets and liabilities offset by the net income for the year. The use of cash for the years ended December 31, 2013 and 2012 was substantially a result of the net loss for the period offset by non-cash expense items.

Our investing activities used \$3.8 million during the year ended December 31, 2014 compared to \$2.1 million of cash used in the year ended December 31, 2013 and \$0.3 million of cash used in the year ended December 31, 2012. The funds used during the year ended December 31, 2014 were for the purchase of products (see Note 19 to the Company's Condensed Consolidated Financial Statements) and capital expenditures related to additional computer equipment and scientific equipment and improvements incurred to expand our R & D. In 2013, we used \$1.8 million to acquire econazole nitrate cream 1%, which we launched in September 2013. The remaining funds used in both 2013 and 2012 were for additional equipment and related services for our analytical and compounding functions, packaging and filling lines.

Our financing activities provided \$164.5 million of cash during the year ended December 31, 2014 compared to \$2.3 million of cash in the years ended December 31, 2013 and 2012. The cash provided for the year ended December 31, 2014 was mainly \$139 million net proceeds from the Notes, \$24.9 million net proceeds from the public offering of common stock and \$0.8 million proceeds from the exercise of common stock warrants and options. The cash provided for the year ended December 31, 2013 was primarily related to the \$2.0 million we drew down on our existing credit line in 2013. The cash provided for the year ended December 31, 2012 was primarily attributable to the sale of our treasury stock, in addition to the \$0.9 million of proceeds from the drawdown of our credit facility, which was offset by the repayment of the note payable to a related party of \$0.5 million as a result of the termination of the existing credit facility.

#### Off-Balance Sheet Arrangements

We have no significant off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to our shareholders.

#### Contractual Obligations

As more fully described under Item 2, Properties, we lease the facilities that we occupy in one building in Buena, New Jersey, a warehouse in Vineland, New Jersey and we have executed a lease to occupy office space in Iselin, New Jersey. Our remaining obligations under these leases are summarized in the table below.

As of December 31, 2014, our principal outstanding debt obligation was related to our Notes. We had an additional \$3.2 million outstanding loans under our GE Capital Credit Agreement at December 31, 2014.

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In consideration for the purchase of the portfolio of products we acquired from Astra Zeneca, we will be required to pay an additional \$6.0 million upon the occurrence of the first milestone event, related to our first regulatory filing with the FDA. We expect this payment to be made in 2015.

Contractual Obligations	Payments Due by Period (in thousands)				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Convertible Senior Notes	\$ 143,750	\$ -	\$ -	\$ 143,750	\$ -
Capital Lease	202	131	71	-	-
Operating Lease	2,940	278	828	986	848
Purchase Obligations	6,000	6,000	-	-	-
Line of Credit	3,160	-	-	3,160	-
Total	\$ 156,052	\$ 6,409	\$ 899	\$ 147,896	\$ 848



### Critical Accounting Policies and Estimates

Our consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles, which require us to make subjective decisions, assessments and estimates about the effect of matters that are inherently uncertain. As the number of variables and assumptions affecting the judgment increases, such judgments become even more subjective. While we believe our assumptions are reasonable and appropriate, actual results may be materially different than estimated.

#### *Fair Value of Financial Instruments*

The Company measures fair value in accordance with ASC 820-10, "Fair Value Measurements and Disclosures" (formerly SFAS 157, "Fair Value Measurements"). ASC 820-10 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820-10 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

**Level 1 Inputs:** Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.

**Level 2 Inputs:** Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.

**Level 3 Inputs:** Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date. The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The Company measures its derivative liability at fair value. The derivative convertible option related to Convertible Notes issued December 16, 2014 was valued using the "with" and "without analysis. A "with" and "without" analysis is a standard valuation technique for valuing embedded derivatives by first considering the value of the Convertible Notes with the option and then considering the value of the Convertible Notes without the option. The difference is the fair value of the embedded derivatives. The convertible note derivative is classified within Level 3 because it is valued

using the “with” and “without” method, which does utilize inputs that are unobservable in the market.

*Allowance for Doubtful Accounts*

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

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

*Revenue Recognition*

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

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

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

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

*Revenue and Provision for Sales Returns and Allowances*

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

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

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

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

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

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

*Derivatives*

The Company accounts for its derivative instruments in accordance with ASC 815-10, “Derivatives and Hedging” (“ASC 815-10”). ASC 815-10 establishes accounting and reporting standards requiring that derivative instruments, including derivative instruments embedded in other contracts, be recorded on the balance sheet as either an asset or liability measured at its fair value. ASC 815-10 also requires that changes in the fair value of derivative instruments be recognized currently in results of operations unless specific hedge accounting criteria are met. The Company has not entered into hedging activities to date. The Company recognizes all derivative instruments as either assets or liabilities in the consolidated balance sheets at their respective fair values. The Company's derivative instruments include the embedded convertible option of its Notes issued December 16, 2014 (as defined in Note 6), all of which have been recorded as a liability at fair value, and are revalued at each reporting date, with changes in the fair value of the instruments included in the consolidated statements of operations as non-operating income (expense).

### *Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include derivatives, SRA allowances, allowances for excess and obsolete inventories, allowances for doubtful accounts, provisions for income taxes and related deferred tax asset valuation allowances, stock based compensation and accruals for environmental cleanup and remediation costs. Actual results could differ from those estimates.

### Recent Accounting Pronouncements

In May 2014, FASB issued Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers”. This ASU is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. This ASU is effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. Accordingly, the Company will adopt this ASU on January 1, 2017. Companies may use either a full retrospective or modified retrospective approach to adopt this ASU and management is currently evaluating which transition approach to use. The Company is currently evaluating the impact of ASU 2014-09.

In August 2014, FASB issued Accounting Standards Update (“ASU”) 2014-15, “Presentation of Financial Statements — Going Concern: Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern”. This ASU requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity’s ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable) and provide related disclosures. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2014-15.

### **Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

As of December 31, 2014, our principal debt obligation was related to our Notes. Interest accrues at a fixed rate of 3.75% on the outstanding principal amount of the Notes and is paid semi-annually every June 15 and December 15 until the Notes mature on December 15, 2019. Since the interest rate is fixed, we have no market risk related to the

Notes.

Our revolving Credit and Security Agreement with GECC calls for interest to accrue based on a premium above either the current prime rate or current LIBOR rates. Therefore, borrowings pursuant to this revolving credit facility would be subject to market risk. However, as of December 31, 2014, we had no outstanding loans and therefore no market risk related to this revolving credit facility.

Our financial instruments include cash and cash equivalents, accounts receivable, accounts payable and the Notes. The fair values of cash and cash equivalents, accounts receivable and accounts payable approximate book value because of the short maturity of these instruments. Based on the closing price of our common stock as of December 31, 2014, the fair value of our Notes was approximately \$141.5 million compared to their face value of \$143.75 million as of December 31, 2014. However, this variance is due to the conversion feature in the Notes rather than to changes in market interest rates. As noted above, the Notes carry a fixed interest rate and therefore do not subject us to interest rate risk. As a result in the change in fair value, we recorded a \$2.3 million change in the fair value of the derivative liability on our consolidated statements of operations.

At December 31, 2014, the bulk of our cash and cash equivalents was invested in overnight instruments, the interest rates of which may change daily. Accordingly, these overnight investments are subject to market risk.

## **Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

See Index to Financial Statements on page F-1.

## **Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## **Item 9A. CONTROLS AND PROCEDURES**

(a) *Evaluation of Disclosure Controls and Procedures.* Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were 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 SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(b) *Changes in Internal Controls.* There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the fourth quarter of our last fiscal year that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The Company's internal control over financial reporting includes those policies and procedures that:



pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on our assessment, management believes that, as of December 31, 2014, the Company's internal control over financial reporting is effective based on those criteria.

Eisner Amper LLP, the independent registered public accounting firm that audited the consolidated financial statements in this Annual Report on Form 10-K for the year ended December 31, 2014, has issued a report concerning the effectiveness of our internal control over financial reporting for that year, which is included in Part II, Item 8 of this Form 10-K.

#### **Item 9B. OTHER INFORMATION**

None.

### **PART III**

#### **Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Management and Corporate Governance Matters," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Code of Conduct and Ethics" in the Company's Proxy Statement for the 2015 Annual Meeting of Stockholders.

#### **Item 11. EXECUTIVE COMPENSATION**

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Executive Officer and Director Compensation," "Compensation Discussion and Analysis," "Management and Corporate Governance Matters," "Compensation Committee Report" and "Compensation Discussion and Analysis" in the Company's Proxy Statement for the 2015 Annual Meeting of Stockholders.

**Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Company’s Proxy Statement for the 2015 Annual Meeting of Stockholders.

**Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Certain Relationships and Related Person Transactions” and “Management and Corporate Governance” in the Company’s Proxy Statement for the 2015 Annual Meeting of Stockholders.

**Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Independent Registered Public Accounting Firm” in the Company’s Proxy Statement for the 2015 Annual Meeting of Stockholders.

**PART IV**

**Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this annual report on Form 10-K:

(a)(1) See “Index to Consolidated Financial Statements and Financial Statement Schedules” at Item 8 to this Annual Report on Form 10-K.

(a)(2) Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

(a)(3) The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibits

(3.1) Amended and Restated Certificate of Incorporation of IGI Laboratories, Inc., dated May 7, 2008 (incorporated by reference to Exhibit 3.1 to the Company’s Report on Form 8-K, filed May 12, 2008).

(3.2) Amended and Restated Bylaws of IGI Laboratories, Inc., effective May 7, 2008 (incorporated by reference to Exhibit 3.2 to the Company’s Report on Form 8-K, filed May 12, 2008).

(4.1) Specimen stock certificate for shares of Common Stock, par value \$.01 per share (incorporated by reference to Exhibit 4 to the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2000, filed March 28, 2001 (“the 2000 Form 10-K”)).

(4.2) Indenture dated as of December 16, 2014, by and between IGI Laboratories, Inc. and Wilmington Trust, National Association (incorporated by reference to Exhibit 4.1 to the Company’s Report on Form 8-K, filed December 17, 2014).

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- (10.1)# IGI, Inc. 1998 Directors Stock Plan, as amended (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 (Registration No. 333-160342), filed June 30, 2009).
- (10.2)# IGI, Inc. 1999 Director Stock Option Plan, as amended (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8 (Registration No. 333-160342), filed June 30, 2009).
- (10.3)# IGI, Inc. 1999 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration No. 333-160342), filed June 30, 2009).
- (10.4)# IGI Laboratories, Inc. 2009 Equity Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed June 4, 2014).
- (10.5)# Form of Non-Qualified Stock Option Agreement under the IGI Laboratories, Inc. 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed July 2, 2009).
- (10.6)# Form of Stock Option Award Agreement under the IGI Laboratories, Inc. 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed July 20, 2011).

- (10.7)# Form of Award Agreement for Restricted Shares under the IGI Laboratories, Inc. 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Report on Form 8-K, filed July 2, 2009)
- (10.8)# Indemnification Agreement by and between IGI Laboratories, Inc. and Joyce Erony, dated March 13, 2009 (incorporated by reference Exhibit 10.10 to the Company's Report on Form 8-K, filed March 19, 2009 (the "March 2009 8-K")).
- (10.9)# Form of Indemnification Agreement for Certain Directors (incorporated by reference to Exhibit 10.11 to the March 2009 8-K).
- (10.10)# Employment Agreement dated July 14, 2011 between IGI Laboratories, Inc. and Jenniffer Collins (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed July 20, 2011).
- (10.11)# Employment Agreement dated July 30, 2012 between IGI Laboratories, Inc. and Jason Grenfell-Gardner (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed July 30, 2012).
- (10.12)# Separation of Employment Agreement and General Release dated August 14, 2012 between IGI Laboratories, Inc. and Charles Moore (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed August 14, 2012).
- (10.13)+ Purchase and Sale Agreement between the Company and Prasco, LLC for the purchase of econazole nitrate cream 1%, dated February 1, 2013, (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed August 9, 2013).
- (10.14) Asset Purchase Agreement dated as of September 30, 2014, by and between IGI Laboratories, Inc. and Valeant Pharmaceuticals North America, LLC and Valeant Pharmaceuticals Luxembourg SARL (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed October 1, 2014).
- (10.15) Asset Purchase Agreement dated as of September 30, 2014, by and between IGI Laboratories, Inc. and Valeant Pharmaceuticals North America, LLC and Valeant Pharmaceuticals Luxembourg SARL (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed October 1, 2014).
- (10.16)+ Asset Purchase Agreement dated as of September 24, 2014, by and between IGI Laboratories, Inc. and AstraZeneca Pharmaceuticals LP (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 10-Q, filed November 13, 2014).
- (10.17) Credit Agreement dated as of November 18, 2014, by and among IGI Laboratories, Inc., Igen, Inc., and IGI Labs, Inc. as Borrowers, the other Persons party thereto that are designated as Credit Parties, General Electric Capital Corporation as Agent for all Lenders, GE Capital Bank as a Lender, and the other financial institutions party thereto as Lenders (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed November 24, 2014).
- (10.18) Guaranty and Security Agreement dated as of November 18, 2014, by and among IGI Laboratories, Inc., Igen, Inc., and IGI Labs, Inc. as Borrowers and each other Grantor from time to time party thereto in favor of General Electric Capital Corporation as Agent (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed November 24, 2014).
- (10.19)

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Purchase Agreement dated December 10, 2014, by and between IGI Laboratories, Inc. and the initial purchasers set forth on Schedule 1 thereto (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed December 17, 2014).

(21)\* List of Subsidiaries.

(23.1)\* Consent of EisnerAmper LLP.

- (31.1)\* Certification of the President and Chief Executive Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- (31.2)\* Certification of the Chief Financial Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- (32.1)\* Certification of the President and Chief Executive Officer and of the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- The following financial information from this Annual Report on Form 10-K for the year ended December 31, 2014, formatted in XBRL (Extensible Business Reporting Language) and furnished electronically herewith:
- (101)\* (i) the Consolidated Statements of Operations; (ii) the Consolidated Balance Sheets; (iii) the Consolidated Statements of Cash Flows; and (iv) the Notes to Consolidated Financial Statements, tagged as blocks of text.

\*Filed herewith.

#Indicates management contract or compensatory plan.

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



**SIGNATURES**

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

IGI Laboratories, Inc.

Date: March 16, 2015 By: /s/ Jason Grenfell-Gardner  
 Jason Grenfell-Gardner  
 President and Chief Executive Officer

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

Signature	Title	Date
/s/ Jason Grenfell-Gardner Jason Grenfell-Gardner	Director, President and Chief Executive Officer (Principal Executive Officer)	March 16, 2015
/s/ Jenniffer Collins Jenniffer Collins	Chief Financial Officer (Principal Financial Officer)	March 16, 2015
/s/ Steven Koehler Steven Koehler	Director	March 16, 2015
/s/ James Gale James Gale	Director	March 16, 2015
/s/ Narendra Borkar Narendra Borkar	Director	March 16, 2015
/s/ Bhaskar Chaudhuri Bhaskar Chaudhuri	Director	March 16, 2015

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders

IGI Laboratories, Inc. and subsidiaries

We have audited the accompanying consolidated balance sheets of IGI Laboratories, Inc. and subsidiaries (the “Company”) as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the years in the three-year period ended December 31, 2014. The financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of IGI Laboratories, Inc. and subsidiaries as of December 31, 2014 and 2013, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), IGI Laboratories, Inc. and subsidiaries internal control over financial reporting as of December 31, 2014, based on criteria established in the 1992 Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”), and our report dated March 16, 2015 expressed an unqualified opinion thereon.

In connection with our audits of the consolidated financial statements referred to above, we also audited Schedule II - Valuation and Qualifying Accounts for each of the years in the three-year period ended December 31, 2014. In our opinion, this financial schedule, when considered in relation to the consolidated financial statements taken as a whole, presents fairly, in all material respects, the information stated therein.

/s/ EisnerAmper LLP

Iselin, New Jersey

March 16, 2015

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders

IGI Laboratories, Inc. and subsidiaries

We have audited IGI Laboratories, Inc. and subsidiaries (the “Company”) internal control over financial reporting as of December 31, 2014, based on criteria established in the 1992 *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company’s 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 generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control 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.

In our opinion, IGI Laboratories, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in the 1992 *Internal Control - Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of IGI Laboratories, Inc. and subsidiaries as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2014, and our report dated, March 16, 2015, expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

Iselin, New Jersey

March 16, 2015

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**IGI LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****(in thousands, except share and per share information)**

	December 31, 2014	December 31, 2013
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 158,883	\$ 2,101
Accounts receivable, net	14,366	4,947
Inventories	2,784	2,869
Prepaid expenses and other receivables	1,185	641
Total current assets	177,218	10,558
Property, plant and equipment, net	3,262	2,623
Product acquisition costs, net	10,604	1,766
Debt issuance costs, net	5,132	69
Other	862	411
Total assets	\$ 197,078	\$ 15,427
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,643	\$ 1,523
Accrued expenses	5,141	2,915
Payable for product acquisition costs	6,000	-
Deferred income, current	87	768
Capital lease obligation, current	131	15
Total current liabilities	13,002	5,221
Convertible 3.75% senior notes, net of debt discount (face of \$143,750)	100,311	-
Fair value of derivative liability - convertible 3.75% senior notes	41,400	-
Note payable, bank	3,160	3,000
Other long term liabilities	71	15
Total liabilities	157,944	8,236
Stockholders' equity:		
Series A Convertible Preferred stock, \$0.01 par value, 100 shares authorized; 0 shares issued and outstanding as of December 31, 2014 and 2013, respectively	-	-
Series C Convertible Preferred stock, \$0.01 par value, 1,550 shares authorized; 0 shares issued and outstanding as of December 31, 2014 and 2013, respectively	-	-
Common stock, \$0.01 par value, 60,000,000 shares authorized; 52,819,787 and 46,748,575 shares issued and outstanding as of December 31, 2014 and December 31, 2013, respectively	548	487

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Additional paid-in capital	78,172	51,541
Accumulated deficit	(39,586 )	(44,837 )
Total stockholders' equity	39,134	7,191
Total liabilities and stockholders' equity	\$ 197,078	\$ 15,427

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

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**IGI LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS****For the years ended December 31, 2014, 2013 and 2012****(in thousands, except shares and per share information)**

	2014	2013	2012
Revenues:			
Product sales, net	\$32,104	\$16,981	\$6,545
Research and development income	1,490	1,094	1,931
Licensing, royalty and other revenue	146	149	87
Total revenues	33,740	18,224	8,563
Costs and Expenses:			
Cost of revenues	16,948	12,079	5,787
Selling, general and administrative expenses	5,976	3,484	3,078
Product development and research expenses	6,910	2,743	2,834
Total costs and expenses	29,834	18,306	11,699
Operating income (loss)	3,906	(82)	(3,136)
Other Income (Expense):			
Change in the fair value of derivative liability	2,300	-	-
Interest and other expense, net	(782)	(199)	(975)
Income (loss) before income tax expense (benefit)	5,424	(281)	(4,111)
Income tax expense (benefit)	173	(197)	(184)
Net income (loss)	5,251	(84)	(3,927)
Preferred stock dividend	-	(1,308)	-
Net income (loss) attributable to common stockholders	\$5,251	\$(1,392)	\$(3,927)
Basic income (loss) per share	\$0.11	\$(0.03)	\$(0.10)
Diluted income (loss) per share	\$0.09	\$(0.03)	\$(0.10)
Weighted average shares of common stock outstanding:			
Basic	49,817,721	43,517,640	39,786,446
Diluted	64,207,190	43,517,640	39,786,446

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



**IGI LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****For the years ended December 31, 2014, 2013 and 2012****(in thousands)**

	2014	2013	2012
Cash flows from operating activities:			
Net income (loss)	\$5,251	\$(84 )	\$(3,927)
Reconciliation of net income (loss) to net cash used in operating activities:			
Depreciation and amortization of fixed assets	415	375	357
Amortization of license fee	100	100	100
Provision for write down of inventory	228	110	138
Issuance of stock to consultant	80		
Stock based compensation expense	823	536	378
Amortization of debt issuance costs	107	31	862
Amortization of product acquisition costs	120	60	-
Amortization of debt discount on convertible 3.75% senior notes	261	-	-
Change in the fair value of derivative liability	(2,300 )	-	-
Loss on abandonment of property	-	-	9
Changes in operating assets and liabilities:			
Accounts receivable	(9,419 )	(3,370)	(369 )
Inventories	(143 )	(1,206)	(716 )
Prepaid expenses and other current receivables	(1,075 )	(402 )	119
Accounts payable and accrued expenses	2,346	2,528	671
Deferred income	(685 )	704	5
Net cash used in operating activities	(3,891 )	(618 )	(2,373)
Cash flows from investing activities:			
Capital expenditures	(834 )	(287 )	(342 )
Product acquisition costs	(2,958 )	(1,826)	-
Net cash used in investing activities	(3,792 )	(2,113)	(342 )
Cash flows from financing activities:			
Proceeds from convertible 3.75% senior notes, net of \$4,765	138,985	-	-
Proceeds from issuance of stock, net	24,858	-	-
Proceeds from note payable, net of debt issuance costs	2,755	2,000	886
Repayment of note payable	(3,000 )	-	-
Repayment of note payable, related party	-	-	(500 )
(Expenses of) proceeds from sale of treasury stock, net of expenses	-	(63 )	1,963
Proceeds from exercise of common stock options and warrants	837	376	39
Principal payments on capital lease obligations	(64 )	(17 )	(51 )
Excess tax benefits from stock compensation	94	-	-

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Net cash provided by financing activities	164,465	2,296	2,337
Net increase (decrease) in cash and cash equivalents	156,782	(435 )	(378 )
Cash and cash equivalents at beginning of year	2,101	2,536	2,914
Cash and cash equivalents at end of year	\$158,883	\$2,101	\$2,536
Supplemental Cash flow information:			
Cash payments for interest	\$178	\$142	\$99
Cash payments for (receipts from) income taxes	23	(194 )	(184 )
Non cash investing and financing transactions:			
Bifurcation of derivative from convertible 3.75% senior notes	41,400	-	-
Payable related to product acquisition costs	6,000	-	-
Common stock issued for conversion of Series C Convertible Preferred stock	-	2,825	-
Common stock issued for conversion of Series A Convertible Preferred stock	-	500	-
Equipment financed through capital lease	-	20	30
Issuance of restricted stock	-	3	1
Forfeiture of restricted stock	-	-	(2 )
Issuance of warrants	-	-	209

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

**IGI LABORATORIES, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**
**For the years ended December 31, 2014, 2013 and 2012**
**(in thousands, except share information)**

	Series A Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In Capital		Accumulated Deficit	Treasury Stock	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Stock	Equity	
Balance, December 31, 2011	50	\$ 500	1,550	\$ 1,517	41,463,836	\$ 415	\$ 46,246	\$(39,518 )	\$(1,395 )	\$ 7,765	
Stock based compensation expense							378			378	
Restricted stock issuance					109,748	1	(1 )			-	
Restricted stock forfeiture					(177,084 )	(2 )	2			-	
Stock options exercised					40,000		26			26	
Stock warrants exercised					1,268,532	13				13	
Sale of treasury stock, net of expenses of \$36						19	549		1,395	1,963	
Fair value of warrants issued							209			209	
Net loss	-	-	-	-	-	-	-	(3,927 )	-	(3,927 )	
Balance, December 31, 2012	50	\$ 500	1,550	\$ 1,517	42,705,032	\$ 446	\$ 47,409	\$(43,445 )	\$-	\$ 6,427	
Stock based compensation expense							536			536	
Restricted stock issuance					325,000	3	(3 )			-	
					427,713	5	231			236	

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Stock warrants exercised										
Stock options exercised				129,336	1	138				139
Costs related to stock issuance						(63 )				(63 )
Common stock issued upon conversion of Series A	(50 )	(500 )		500,000	5	495				-
Convertible Preferred stock										
Common stock issued upon conversion of Series C										-
Convertible Preferred stock including deemed dividend of \$1,308			(1,550)	(1,517)	2,661,494	27	2,798	(1,308 )		-
Net loss	-	-	-	-	-	-	-	(84 )	-	(84 )
Balance, December 31, 2013	-	\$-	-	\$-	46,748,575	\$ 487	\$ 51,541	\$(44,837 )	\$-	\$ 7,191
Issuance of stock pursuant to a public offering, net of associated fees of \$1,868				5,347,500	53	24,805				24,858
Issuance of stock to consultant				10,000		80				80
Stock based compensation expense						823				823
Stock warrants exercised				270,546	3	325				328
Stock options exercised				443,166	5	504				509
Excess tax benefits from stock compensation						94				94
Net income	-	-	-	-	-	-	-	5,251	-	5,251
	-	\$-	-	\$-	52,819,787	\$ 548	\$ 78,172	\$(39,586 )	\$-	\$ 39,134

Balance,  
December 31,  
2014

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

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## **IGI LABORATORIES, INC. AND SUBSIDIARIES**

### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

#### **1. Summary of Significant Accounting Policies**

##### *Nature of the Business*

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

Currently, the Company has two platforms for growth:

Developing, manufacturing, and marketing a portfolio of generic pharmaceutical products under our own label in topical, injectable, complex and ophthalmic dosage forms; and,

- Managing our current contract manufacturing and formulation services business.

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

To date, we have filed 24 Abbreviated New Drug Applications, or ANDAs, with the United States Food and Drug Administration, or FDA, for additional pharmaceutical products. We expect to continue to expand our presence in the generic pharmaceutical market through the filing of additional ANDAs with the FDA and the subsequent launch of products as these applications are approved. Our target is to file at least 20 ANDAs in 2015 through our internal research and development program. On March 12, 2014, the Company received its first approval from the FDA for an ANDA. The FDA has approved IGI's application for lidocaine hydrochloride USP 4% topical solution. On May 7, 2014, the Company received tentative approval from the FDA for its ANDA for diclofenac sodium 1.5% topical solution. On June 26, 2014, the Company executed an agreement to enable it to launch the product in March 2015



after final FDA approval. We will also seek to license or acquire further products, intellectual property, or ANDAs to expand our portfolio.

On September 24, 2014, we acquired from AstraZeneca Pharmaceuticals LP ANDAs and NDAs associated with eighteen products, seventeen of which were injectable products. On September 30, 2014, we acquired ANDAs and NDAs associated with two ophthalmic products from Valeant Pharmaceuticals North America LLC and Valeant Pharmaceuticals Luxembourg SARL (Valeant), in addition to the exclusive right to acquire three additional injectable products from Valeant. One of these additional products was acquired from Valeant on November 18, 2014.

On February 1, 2013, we acquired assets and intellectual property, including an ANDA, for econazole nitrate cream 1%, which we launched in September 2013.

IGI also develops, manufactures, fills, and packages topical semi-solid and liquid products for branded and generic pharmaceutical customers, as well as the OTC and cosmetic markets. These products are used in a wide range of applications from cosmetics and cosmeceuticals to the prescription treatment of conditions like dermatitis, psoriasis, and eczema. IGI is currently exploring various options to enable us to expand our development and manufacturing capabilities to include sterile injectable and ophthalmic products.

#### *Principles of Consolidation*

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

#### *Cash Equivalents*

Cash equivalents consist of short-term investments, which have original maturities of 90 days or less. These include direct obligations of the U.S. Treasury, including bills, notes and bonds, as well as obligations issued or guaranteed by agencies or instrumentalities of the U.S. government including government-sponsored enterprises (GSEs).

#### *Fair Value of Financial Instruments*

The carrying amounts of cash and cash equivalents, trade receivables, restricted cash, notes payable, accounts payable, capital leases and other accrued liabilities at December 31, 2014 approximate their fair value for all periods presented.

The Company measures fair value in accordance with ASC 820-10, "Fair Value Measurements and Disclosures". ASC 820-10 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820-10 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

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Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.

Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date. The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The Company measures its derivative liability at fair value. The derivative convertible option related to Convertible Notes issued December 16, 2014 was valued using the “with” and “without” analysis. A “with” and “without” analysis is a standard valuation technique for valuing embedded derivatives by first considering the value of the Convertible Notes with the option and then considering the value of the Convertible Notes without the option. The difference is the fair value of the embedded derivatives. The convertible note derivative is classified within Level 3 because it is valued using the “with” and “without” method, which does utilize inputs that are unobservable in the market.

The following table presents the Company’s assets and liabilities measured at fair value on a recurring basis as of December 31, 2014:

		Fair value measurement at reporting date using		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Derivative liabilities on account of convertible notes	Balance			
As of December 31, 2014	\$41,400	-	-	\$ 41,400

Based on the closing price of the Company’s common stock as of December 31, 2014, the fair value of the Notes was approximately \$141.5 million compared to their face value of \$143.75 million as of December 31, 2014. However, this variance is due to the conversion feature in the Notes rather than to changes in market interest rates. The Notes

carry a fixed interest rate and therefore do not subject the Company to interest rate risk. As a result in the change in fair value, the Company recorded a \$2.3 million change in the fair value of the derivative liability on the consolidated statements of operations.

#### *Accounts Receivable and Allowance for Doubtful Accounts*

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

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

#### *Concentration of Credit Risk*

Financial instruments, which subject the Company to concentrations of credit risk, consist primarily of cash equivalents and trade receivables. These include direct obligations of the U.S. Treasury, including bills, notes and bonds, as well as obligations issued or guaranteed by agencies or instrumentalities of the U.S. government including government-sponsored enterprises (GSEs), which are not federally insured.

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

In 2014, the Company had sales to two customers which individually accounted for more than 10% of the Company's total revenue. These customers had sales of \$10.5 million and \$4.4 million, respectively, and represented 44% of total revenues in the aggregate. Accounts receivable related to the Company's major customers comprised 42% of all accounts receivable as of December 31, 2014.

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

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

The Company had net revenue from one product, econazole nitrate cream, which accounted for 38% of total revenues in 2014. The Company did not have significant revenue from any one product in 2013 or 2012.

#### *Inventories*

Inventories are valued at the lower of cost, using the first-in, first-out ("FIFO") method, or market. The company records an inventory reserve for losses associated with dated and expired raw materials. This reserve is based on management's current knowledge with respect to inventory levels, planned production, and extension capabilities of materials on hand. Management does not believe the Company's inventory is subject to significant risk of obsolescence in the near term. Reserve for obsolescence included in inventory at December 31, 2014 and 2013 were \$0.2 million and \$0.2 million respectively.

*Property, Plant and Equipment*

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

**Useful Lives**

Buildings and improvements	10 - 30 years
Machinery and equipment	3 - 10 years

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

*Intangible Assets*

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

*Long-Lived Assets*

In accordance with the provisions of ASC 360-10-55, the Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. In performing such review for recoverability, the Company compares expected future cash flows of assets to the carrying value of the long-lived assets and related identifiable intangibles. If the expected future cash flows (undiscounted) are less than the carrying amount of such assets, the Company recognizes an impairment loss for the difference between the carrying value of the assets and their estimated fair value, with fair values being determined using projected discounted cash flows at the lowest level of cash flows identifiable in relation to the assets being reviewed. As of December 31, 2014, no impairments existed.

*Accrued Expenses*

Accrued expenses represent various obligations of the Company including certain operating expenses and taxes payable. For the fiscal year ended December 31, 2014, the largest component of accrued expenses was accrued wholesaler fees of \$1.7 million, accrued payroll of \$1.4 million, accrued royalties of \$0.7 million, accrued consulting fees of \$0.3 million, accrued interest expense of \$0.2 million and accrued directors' fees of \$0.1 million. For the fiscal year ended December 31, 2013, the largest component of accrued expenses was accrued royalties of \$0.9 million, accrued payroll of \$0.7 million, accrued wholesaler fees of \$0.6 million and accrued directors' fees of \$0.2 million.

#### *License Fee*

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

#### *Accounting for Environmental Costs*

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

#### *Income Taxes*

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

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

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### *Revenue Recognition*

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

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

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

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

### *Revenue and Provision for Sales Returns and Allowances*

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

The provision for chargebacks is our most significant sales allowance. A chargeback represents an amount payable in the future to a wholesaler for the difference between the invoice price paid to the Company by our wholesale customer for a particular product and the negotiated contract price that the wholesaler's customer pays for that product. The

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

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

### Gross-To-Net Sales Deductions

	Years Ended December 31,		
	2014	2013	2012
	(in thousands)		
Gross IGI product sales	\$ 51,136	\$ 15,001	\$ 18
Reduction to gross product sales:			
Chargebacks and billbacks	(26,940 )	(6,050 )	—
Sales discounts and other allowances	(4,366 )	(1,593 )	(1 )
Total reduction to gross product sales	\$(31,306 )	\$(7,643 )	\$(1 )
Net IGI product sales	\$ 19,830	\$ 7,358	\$ 17

Accounts receivable are presented net of SRA balances of \$5.6 million and \$1.9 at December 31, 2014 and 2013, respectively. Accounts payable and accrued expenses include \$1.7 million and \$0.6 at December 31, 2014 and 2013, respectively, for certain fees related to services provided by the wholesalers. Wholesale fees of \$3.1 million, \$0.9 million and \$0 for the years ended December 31, 2014, 2013 and 2012, respectively, were included in cost of goods sold.

In addition, in connection with four of the six products the Company currently manufactures, markets and distributes in its own label, in accordance with an agreement entered into in December of 2011, the Company is required to pay a royalty calculated on the basis of net sales to one of its pharmaceutical partners. The royalty is calculated based on contracted terms of 40% of net sales for the four products which is to be paid quarterly to the pharmaceutical partner. In accordance with the agreement, net sales excludes fees related to services provided by the wholesalers. Accounts payable and accrued expenses include \$0.7 million and \$0.9 at December 31, 2014 and 2013, respectively, related to these royalties. Royalty expense of \$3.6 million, \$2.6 million and \$0 was included in cost of goods sold for the twelve months ended December 31, 2014, 2013, and 2012 respectively. The Company includes significant estimates to arrive at net product sales arising from wholesaler chargebacks, Medicaid and Medicare rebates, allowances and other pricing and promotional programs.

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

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

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

Licensing and Royalty Income: Revenues earned under licensing or sublicensing contracts are recognized as earned in accordance with the terms of the agreements. The Company recognizes royalty revenue based on royalty reports received from the licensee. The Company does not have current plans to have meaningful revenue from licensing and royalty agreements in 2015.

#### *Stock-Based Compensation*

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

*Debt Issuance Costs*

Expenses related to debt financing activities are capitalized and amortized on an effective interest method, over the term of the loan. See detailed amounts per year in Notes 6, 7 and 8.

*Product Development and Research*

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

*Shipping and Handling Costs*

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

*Net Income (Loss) per Common Share*

Basic net income (loss) per share of common stock is computed based on the weighted average number of shares of common stock outstanding during the period. Diluted net income (loss) per share of common stock is computed using the weighted average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period. Potential dilutive common stock equivalents include shares issuable upon the conversion of the convertible 3.75% senior notes and the exercise of options and warrants and the conversion of preferred stock. Due to the net loss for the years ended December 31, 2013 and 2012, the effect of the Company's potential dilutive common stock equivalents was anti-dilutive for each year; as a result, the basic and diluted weighted average number of common shares outstanding and net loss per common share are the same. As of December 31, 2013, the shares of common stock issuable in connection with stock options and warrants of 2,998,406, and as of December 31, 2012, the shares of common stock issuable in connection with stock options and warrants and the conversion of preferred stock of 6,445,628 were not included in the diluted income per common share calculation since their effect was anti-dilutive.

**For the years ended December 31, 2014, 2013 and 2012****(in thousands except shares and per share data)**

	2014	2013	2012
Basic earnings per share computation:			
Net income (loss) attributable to common stockholders —basic	\$5,251	\$ (1,392 )	\$ (3,927 )
Weighted average common shares —basic	49,817,721	43,517,640	39,786,446
Basic net income (loss) per share	\$0.11	\$ (0.03 )	\$ (0.10 )
Dilutive earnings per share computation:			
Net income (loss) attributable to common stockholders —basic	\$5,251	\$ (1,392 )	\$ (3,927 )
Interest expense related to convertible 3.75% senior notes	224	-	-
Net income (loss) attributable to common stockholders —diluted	\$5,475	\$ (1,392 )	\$ (3,927 )
Share Computation:			
Weighted average common shares —basic	49,817,721	43,517,640	39,786,446
Effect of convertible 3.75% senior notes	12,732,168	-	-
Effect of dilutive stock options and warrants	1,657,301	-	-
Weighted average common shares outstanding —diluted	64,207,190	43,517,640	39,786,446
Diluted net income (loss) per share	\$0.09	(\$0.03 )	(\$0.10 )

*Derivatives*

The Company accounts for its derivative instruments in accordance with ASC 815-10, “Derivatives and Hedging” (“ASC 815-10”). ASC 815-10 establishes accounting and reporting standards requiring that derivative instruments, including derivative instruments embedded in other contracts, be recorded on the balance sheet as either an asset or liability measured at its fair value. ASC 815-10 also requires that changes in the fair value of derivative instruments be recognized currently in results of operations unless specific hedge accounting criteria are met. The Company has not entered into hedging activities to date. The Company's derivative liability is the embedded convertible option of its Convertible Notes issued December 16, 2014 (as defined in Note 6), all of which have been recorded as a liability at fair value, and are revalued at each reporting date, with changes in the fair value of the instruments included in the consolidated statements of operations as non-operating income (expense).

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include valuation of the

derivative liability, SRA allowances, allowances for excess and obsolete inventories, allowances for doubtful accounts, provisions for income taxes and related deferred tax asset valuation allowances, stock based compensation and accruals for environmental cleanup and remediation costs. Actual results could differ from those estimates.

#### *Recent Accounting Pronouncements*

In May 2014, FASB issued Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers”. This ASU is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. This ASU is effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. Accordingly, the Company will adopt this ASU on January 1, 2017. Companies may use either a full retrospective or modified retrospective approach to adopt this ASU and management is currently evaluating which transition approach to use. The Company is currently evaluating the impact of ASU 2014-09.

In August 2014, FASB issued Accounting Standards Update (“ASU”) 2014-15, “Presentation of Financial Statements — Going Concern: Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern”. This ASU requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity’s ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable) and provide related disclosures. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2014-15.

## 2. Liquidity

The Company's principal sources of liquidity are cash and cash equivalents of approximately \$158,883,000 at December 31, 2014, the \$6,840,000 available under the \$10,000,000 credit facility, (See Note 7).

On December 10, 2014, the Company entered into a purchase agreement (the "Purchase Agreement"), pursuant to which the Company agreed to sell its 3.75% Convertible Senior Notes due 2019 (the "Notes") The company received net proceeds of approximately \$139 million after expenses of approximately \$4.8 million upon completion of the transaction. (See Note 6)

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. The Company also has the ability to defer certain product development and other programs, if necessary. The Company believes that our existing capital resources will be sufficient to support its current business plan and operations beyond March 2016.

## 3. License Fee

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

## 4. Inventories

Inventories as of December 31, 2014 and 2013 consisted of:



	2014	2013
	(in thousands)	
Raw materials	\$2,299	\$2,172
Work in progress	140	271
Finished goods	345	426
	\$2,784	\$2,869

## 5. Property, Plant and Equipment

Property, plant and equipment, at cost, as of December 31, 2014 and 2013, consisted of:

	2014	2013
	(in thousands)	
Land	\$257	\$257
Building and improvements	3,775	3,599
Machinery and equipment	4,156	3,375
Construction in progress	225	128
	8,413	7,359
Less accumulated depreciation and amortization	(5,151)	(4,736)
Property, plant and equipment, net	\$3,262	\$2,623

The Company recorded depreciation and amortization expense of \$415,000, \$375,000 and \$357,000 in 2014, 2013 and 2012, respectively.

## 6. Convertible 3.75% Senior Notes

On December 16, 2014, the Company issued \$125 million aggregate principal amount of 3.75% Convertible Senior Notes due 2019, or the Notes. On December 22, 2014, the Company announced the closing of the initial purchasers' exercise in full of their option to purchase an additional \$18.75 million aggregate principal amount. The Notes were offered and sold only to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"). The net proceeds from the sale of the Notes were approximately \$139 million, after deducting underwriting fees and other related expenses of approximately \$4.8 million. Accrued interest in the amount of \$0.2 million related to the Notes was included in accrued expenses.

The Notes bear interest at a fixed rate of 3.75% per year, payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2015 and mature on December 15, 2019, unless earlier repurchased, redeemed or converted. The Notes are convertible into shares of the Company's common stock, cash or a combination thereof. However, if the Company has not received stockholder approvals to increase the number of authorized shares of the Company's common stock and comply with certain listing standards of the NYSE MKT, the Company would be required to satisfy any conversion obligations solely in cash or, at the Company's option subject to certain conditions and limitations, in shares of the Company's common stock. The Notes are convertible at an initial conversion price of approximately \$11.29 per share, which is equivalent to an initial conversion rate of 88.5716 shares per \$1,000 principal amount of Notes, subject to adjustment in certain events, such as distributions of dividends or stock splits. Holders may convert their Notes at their option prior to September 15, 2019, when or if certain conditions have been met or circumstances have occurred, such as the Company's stock price exceeds 130% of the conversion price under the Notes for a designated period of time, or the trading price of the Notes is, for a designated period of time, less than 98% of the closing sale price of the Company's common stock multiplied by the then-current conversion rate of the Notes, or the Company calls Notes for redemption, or certain specified corporate events occur. Holders may also convert their Notes at their option at any time on or after September 15, 2019 and prior to the close of business on the business day immediately preceding the stated maturity date. In addition, following the occurrence of certain changes of control of the Company described in the Indenture governing the Notes or termination of trading of the Company's common stock or other securities into which the Notes are convertible (a "make-whole fundamental change") or the delivery by the Company of a notice of redemption, the conversion rate for a holder who elects to convert its Notes in connection with such make-whole fundamental change or such notice of redemption will increase in certain circumstances. Additionally, subject to certain conditions, the Company may redeem for cash any or all outstanding Notes on or after December 19, 2017 in an amount equal to the outstanding principal amount of such Notes, plus accrued and unpaid interest.

The Notes and any common stock issuable upon conversion of the Notes have not been registered under the Securities Act, applicable state securities laws or the securities laws of any other jurisdiction, and may not be offered or sold in the United States without registration or an applicable exemption from registration requirements. The Company does not intend to file a registration statement for the resale of the Notes or any common stock issuable upon conversion of the Notes, nor shall there be any sale of these securities in any jurisdiction in which such offer, solicitation, or sale would be unlawful.

Since the Company does not have sufficient authorized shares available to share-settle the conversion option in full, the embedded conversion option does not qualify for equity classification and instead is separately valued and accounted for as a derivative liability. On December 16, 2014, the initial value allocated to the derivative liability was \$43.7 million of the \$143.75 million principal amount of the Notes, which represents a discount to the debt to be amortized through interest expense using the effective interest method through the maturity of the Notes. Accordingly, the effective interest rate used to amortize the debt discount on the Notes is 12.94%. During each reporting period, the derivative liability is marked to fair value through the statement of operations. As of December 31, 2014, the derivative liability, which is classified in long-term liability, had a fair value of \$41.4 million. This resulted in a change in the fair value of the derivative liability of \$2.3 million for the year ended December 31, 2014. If the Company receives shareholder approval for the increase in the number of shares of common stock authorized and available for issuance upon conversion of the Notes so the conversion option can be share-settled in full, the conversion option may qualify for equity classification and the bifurcated derivative liability would no longer need to be accounted for as a separate derivative on a prospective basis from the date of reassessment. Any remaining debt discount that arose at the date of debt issuance from the original bifurcation will continue to be amortized through interest expense.

The Notes are being accounted for in accordance with ASC 470-20. Under ASC 470-20, issuers of convertible debt instruments that may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components.

The application of ASC 470-20 resulted in the recognition of \$43.7 million as the value for the liability at December 31, 2014. The remaining unamortized discount and unamortized debt financing costs will be amortized over the remaining term of 4.95 years. At December 31, 2014 the net carrying amount of the liability component and the remaining unamortized debt discount were as follows:

	December 31, 2014 (in thousands)
Face Amount of the Notes	\$ 143,750
Unamortized discount of the liability component	43,439
Carrying amount of the Notes	\$ 100,311

Deferred financing costs associated with the Notes, include fees of \$4.7 million at December 31, 2014. The assumptions used in connection with the valuation of the convertible option of the Notes issued December 16, 2014 utilizing the "with" and "without" method, discussed in Note 2 was as follows:

	Initial Measurement December 16, 2014		Measurement December 31, 2014	
Issue date	12/17/2014		12/17/2014	
Maturity date	12/15/2019		12/15/2019	
Term	4.99		4.92	
Principal (millions)	143.75		143.75	
Coupon	3.75	%	3.75	%
Seniority	Senior unsecured		Senior unsecured	
Conversion shares	88.572		88.572	
Conversion price	\$ 11.29		\$ 11.29	
Stock price	\$9.45		\$8.80	
Risk free rate	1.61	%	1.64	%
Volatility (rounded)	40.00	%	40.00	%

The table below provides a reconciliation of beginning and ending balances for the liability measured at fair value using significant observable and unobservable inputs (Level 3). The table reflects the gain for the year ended December 31, 2014 associated with the decrease in fair value.

	Initial Measurement December 16, 2014	Decrease in Fair Value	December 31, 2014
Fair Value of Convertible Feature of Convertible 3.75% Senior Notes	\$ 43,700	\$ 2,300	\$ 41,400

For the year ended December 31, 2014, the Company recorded the following expenses in relation to the Notes:

December 31,  
2014

(in thousands)

Interest Expense at 3.75% coupon rate	\$	225
Debt Discount Amortization		261
Amortization of deferred financing costs		28
Total interest expense (1)	\$	514

(1) Included within “Interest and other expense, net” on the Consolidated Statements of Operations

## 7. Note Payable – General Electric Capital Corporation

On November 18, 2014, the Company entered into an asset-based revolving senior secured credit facility (the “Credit Agreement”) with General Electric Capital Corporation, as agent (the “Agent”), and GE Capital Bank and the other financial institutions party thereto, as lenders (the “Lenders”), pursuant to which the Lenders agreed to extend credit facilities to the Company (the “Financing”).

To secure payment of the amounts financed under the Credit Agreement, the Company and the Agent entered into a Guaranty and Security Agreement (the “Guaranty and Security Agreement”). Under the terms of the Guaranty and Security Agreement, the Company granted to the Agent, for the benefit of the Lenders and other secured parties, a continuing security interest in and against substantially all of its tangible and intangible assets, except intellectual property, and each of the Company’s direct and indirect future subsidiaries shall guarantee the Company’s obligations under the Credit Agreement.

Under the Credit Agreement, the Company can request revolving loan advances up to an aggregate total amount of \$10,000,000, which may be increased to \$15,000,000 at the request of the Company if certain conditions are met. The Company may also request an incremental facility for revolving loan commitments of up to \$10,000,000. Borrowings under the Credit Agreement may be made as prime rate loans with an applicable margin of 3.0% per annum or 1, 2, 3 or 6 month LIBOR loans with an applicable margin of 4.0% per annum. At December 31, 2014, the interest rate in effect was 4.2%. Availability under the Credit Agreement is calculated as 85% of the book value of eligible accounts at such time multiplied by a liquidity factor, less any reserves established by the Agent. As of December 31, 2014, the outstanding balance of the credit facility was \$3,160,000. In accordance with the Credit Agreement, the Company is required to provide the Lenders information related to working capital by which the Lenders will calculate the available line of credit, defined in the agreement as the Borrowing Base Certificate. As of December 31, 2014, the Company had a remaining availability of \$6,744,000.

The term of the Credit Agreement is up to five years from November 18, 2014. The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, covenants that limit or restrict the Company's ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, or repurchase stock, in each case, subject to customary exceptions for a loan facility of this size and type. In addition, the Credit Agreement contains customary events of default (subject to customary cure periods for certain events of default), including, among others, non-payment, inaccuracy of representations and warranties, covenant defaults, cross-default to material agreements, cross-default to material indebtedness, bankruptcy and insolvency and material judgment defaults. The Company must meet certain financial reporting and audit requirements, as defined by the credit agreement. The Company was in compliance with all other covenants of the Credit Agreement as of December 31, 2014.

In connection with the Financing, the Company paid in full its existing credit facility with Square 1 Bank (Note 8) and executed a Release and Termination Note and Credit Agreement with Square 1 Bank to release the Company from any future obligations under the Credit Agreement executed on August 31, 2012, as amended July 26, 2013.

#### **8. Note Payable – Square 1 Bank**

On August 31, 2012, as amended on July 26, 2013, the Company entered into a Loan and Security Agreement (the *Loan and Security Agreement*) with Square 1 Bank (the *Lender*) pursuant to which the Lender agreed to extend credit facilities to the Company. The Company drew down \$1,000,000 in principal on August 31, 2012, \$1,000,000 in principal on February 5, 2013 and \$1,000,000 in principal on August 2, 2013.

On November 18, 2014, the Company paid in full its existing credit facility with the Lender under the Loan and Security Agreement. The Company recorded amortization expense in the amount of \$42,000 to write-off the remaining unamortized debt issuance costs.

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

In connection with the financing, the Company paid in full its existing credit facility with Amzak Capital Management, LLC (see Note 9 below) and executed a Release and Termination Note and Credit Agreement with Amzak Capital Management, LLC to release the Company from any future obligations under the Credit Agreement executed on December 21, 2010 (the *Amzak Credit Facility*).

## 9. Note Payable – Former Related Party

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

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

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

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

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

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

#### **10. Series A Convertible Preferred Stock**

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

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

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

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

#### **11. Series C Convertible Preferred Stock – 2010 Offering**

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



The Company has a total of 1,000,000 shares of authorized shares of preferred stock, of which 1,550 shares were designated as Series C Convertible Preferred Stock.

Pursuant to the terms of the Certificate of Designation, the shares of Series C Preferred Stock automatically converted into shares of the Company's Common Stock upon the date that the closing price of the Company's Common Stock exceeded three times the closing price on the issuance date for a period of 25 consecutive trading days immediately preceding such date. Accordingly, on December 6, 2013, all of the shares of Series C Convertible Preferred Stock automatically converted into shares of the Company's Common Stock.

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

## **12. Stock-Based Compensation**

The 1999 Director Stock Option Plan, as amended (the "Director Plan"), provides for the grant of stock options to non-employee directors of the Company at an exercise price equal to the fair market value per share on the date of the grant. An aggregate of 1,975,000 shares have been approved and authorized for issuance pursuant to this plan. A total of 2,369,798 options have been granted to non-employee directors through December 31, 2014 and 807,782 of those have been forfeited through December 31, 2014 and returned to the option pool. The options granted under the Director Plan vest in full one year after their respective grant dates and have a maximum term of ten years.

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

On June 26, 2009, the Board of Directors adopted, and the Company's stockholders subsequently approved, the IGI Laboratories, Inc. 2009 Equity Incentive Plan (the "2009 Plan"). The 2009 Plan allows the Company to continue to grant options and restricted stock, as under the 1999 Plan, but also authorizes the Board of Directors to grant a broad range of other equity-based awards, including stock appreciation rights, restricted stock units and performance awards. The 2009 Plan has been created, pursuant to and consistent with the Company's current compensation philosophy, to assist the Company in attracting, retaining and rewarding designated employees, directors, consultants and other service providers of the Company and its subsidiaries and affiliates, in a manner that will be cost efficient to the Company from both an economic and financial accounting perspective. On April 12, 2010, the Board of Directors adopted, and the Company's stockholders subsequently approved, an amendment and restatement of the 2009 Plan to increase the number of shares of Common Stock available for grant under such plan by adding 2,000,000 shares of Common Stock. The 2009 Plan, as amended on May 19, 2010, authorizes up to 4,000,000 shares of the Company's common stock for issuance pursuant to the terms of the 2009 Plan. The maximum number of shares that may be subject to awards made to any individual in any single calendar year under the 2009 Plan is 1,000,000 shares. As of December 31, 2014, options to purchase 2,004,334 shares of common stock were outstanding under the 2009 Plan. As of December 31, 2014, 1,473,748 shares of restricted stock had been granted under the 2009 Plan and 230,420 of those have been forfeited through December 31, 2014 and returned to the pool.

In summary, there are 2,436,334 options outstanding under the 1999 Plan, the Director Plan and the 2009 Plan, collectively as of December 31, 2014.

There are 2,086,820 options available for issuance under the Director Plan, and the 2009 Plan collectively as of December 31, 2014.

### Stock Options

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

Assumptions	2014	2013	2012
Dividend yield	0	% 0	% 0
Risk free interest rate	0.74% - 1.2	% 0.48	% 0.39
Estimated volatility factor	44.0% - 53.0	% 36.9% - 43.1	% 54.5
Expected life	3.2 - 3.3 years	3.2 - 3.3 years	3.2 years

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

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

	<b>Shares</b>	<b>Exercise Price Per Share</b>	<b>Weighted Average Exercise Price</b>
January 1, 2012 shares issuable under options	1,448,016	\$.55 - 1.74	\$ 1.16
Granted	1,551,000	1.02 - 1.18	1.05
Exercised	(40,000 )	.65	0.65
Expired	(15,000 )	.65	0.65
Forfeited	(337,516 )	.55 - 1.52	1.22
December 31, 2012 shares issuable under options	2,606,500	.55 - 1.74	1.10
Granted	247,000	1.04 - 3.03	1.35
Exercised	(129,336 )	1.02 - 1.27	1.08
Expired	—	—	—
Forfeited	(80,664 )	1.10 - 1.74	1.30
December 31, 2013 shares issuable under options	2,643,500	.55 - 3.03	1.12
Granted	397,500	2.96 - 10.55	5.89
Exercised	(443,166 )	.55 - 1.95	1.15
Expired	—		
Forfeited	(161,000 )	1.00 - 5.65	2.71
December 31, 2014 shares issuable under options	2,436,834	0.76 - 10.55	1.79

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2014:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number of Options	Weighted Average Remaining Life (Years )	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
\$ 0.76 to \$ 1.00	97,000	3.04	\$ .78	97,000	\$ .78
1.01 to 1.50	1,887,500	7.14	1.07	1,448,664	1.08
1.51 to 10.55	452,334	8.68	5.02	110,333	1.78
\$0.76 to \$10.55	2,436,834	7.26	\$ 1.79	1,655,997	\$ 1.11

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

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

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

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number of Options	Weighted Average Remaining Life (Years )	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
\$.55 to \$1.00	218,000	5.83	\$ .76	212,000	\$ .75

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1.01 to 1.50	2,213,500	8.43	1.09	564,001	1.21
1.51 to 1.74	175,000	8.01	1.68	175,000	1.68
\$.55 to \$1.74	2,606,500	8.19	\$ 1.10	951,001	\$ 1.19

The Company has recorded an aggregate of \$316,200, \$206,500 and \$156,000 related to its stock option based expenses in cost of sales, product development and research expenses, and selling, general and administrative expenses on the accompanying Consolidated Statements of Operations for the years ended December 31, 2014, 2013 and 2012, respectively.

The aggregate intrinsic value of options outstanding was \$17,103,045 at December 31, 2014, \$5,109,925 at December 31, 2013 and \$82,270 at December 31, 2012. The aggregate intrinsic value of the options exercisable was \$12,738,143 at December 31, 2014, \$2,789,901 at December 31, 2013 and \$62,410 at December 31, 2012. The total intrinsic value of the options exercised during 2014, 2013 and 2012 was \$3,391,030, \$254,779 and \$15,600, respectively.

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A summary of non-vested options at December 31, 2014 and changes during the year ended December 31, 2014 is presented below:

	Options	Weighted Average Grant Date Fair Value
Non-vested options at January 1, 2014	1,191,004	\$ 0.33
Granted	397,500	2.09
Vested	(665,333 )	0.32
Forfeited	(142,334 )	0.87
Non-vested options at December 31, 2014	780,837	\$ 1.12

As of December 31, 2014, there was \$657,500 of total unrecognized compensation cost related to non-vested share-based compensation arrangements under the Plan. The costs will be recognized through December 2017.

#### Restricted Stock

The Company periodically grants restricted stock awards to certain officers and other employees that typically vest one to three years from their grant date. On December 30, 2013, in accordance with the terms of the employment agreement between Jason Grenfell-Gardner, President and CEO, and the Company executed on July 30, 2012, a restricted stock award in the amount of 325,000 shares was granted to Jason Grenfell-Gardner, with one third of the shares of restricted stock vested on December 30, 2013, and the remaining two thirds of the shares of restricted stock vesting in equal amounts on July 30, 2014 and July 30, 2015. The Company recognized \$507,100, \$329,400 and \$222,000, respectively, of compensation expense during the years ended December 31, 2014, 2013 and 2012 related to restricted stock awards. Stock compensation expense is recognized over the vesting period of the restricted stock. At December 31, 2014, the Company had approximately \$114,200 of total unrecognized compensation cost related to non-vested restricted stock, all of which will be recognized through July 2015.

	Number of Restricted Stock	Weighted Average Issuance Price
Non-vested balance at January 1, 2012	626,000	\$ 0.71
Changes during the period:		
Shares granted	109,748	1.00
Shares vested	(529,330 )	0.76
Shares forfeited	(177,084 )	0.70

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Non-vested balance at January 1, 2013	29,334		\$ 1.00
Changes during the period:			
Shares granted	325,000		2.86
Shares vested	(108,333	)	2.86
Shares forfeited	—		
Non-vested balance at December 31, 2013	246,001		\$ 2.64
Changes during the period:			
Shares granted	-		
Shares vested	(137,667	)	2.46
Shares forfeited	-		
Non-vested balance at December 31, 2014	108,334		\$ 2.86

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**13. Stock Warrants**

Stock Warrants as of December 31, 2014, 2013 and 2012 consisted of:

	2014		2013		2012	
	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price
Beginning balance	354,546	\$ 1.21	782,259	\$ 0.85	1,235,877	\$ 0.35
Stock warrants granted	—	—	—	—	814,914	0.29
Stock warrants expired	—	—	—	—	—	—
Stock warrants exercised	(270,546)	1.21	(427,713)	0.55	(1,268,532)	0.01
Ending balance	84,000	\$ 1.21	354,546	\$ 1.21	782,259	\$ 0.85

In connection with the private placement of the Company's Common Stock on December 8, 2010, the Company granted common stock warrants to purchase 338,182 and 16,364 shares, respectively, to each of its two placement agents for \$1.21 per share which expire on December 8, 2015. In 2014, 270,546 of these warrants were exercised, and 84,000 remain unexercised.

In connection with the Credit Agreement with Amzak Capital Management, LLC as more fully described in Note 9, on December 10, 2010, the Company issued a ten-year warrant to purchase 881,331 shares of the Company's Common Stock for \$0.01 per share. The warrant was exercised in full on September 28, 2012.

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

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



**14. Income Taxes**

The Company's current tax expense (benefit) was \$173,000, \$(197,000) and \$(184,000) for the years ended December 31, 2014, 2013 and 2012, respectively. The provision for (benefit from) income taxes attributable to continuing operations before income taxes for the years ended December 31, 2014, 2013 and 2012 is as follows:

	2014	2013	2012
	(in thousands)		
Current tax expense (benefit):			
Federal	\$97	\$-	\$-
State and local	76	(197)	(184)
Total current tax expense (benefit)	173	(197)	(184)
Deferred tax expense (benefit):			
Federal	-	-	-
State and local	-	-	-
Total deferred tax expense (benefit)	-	-	-
Total income tax expense (benefit)	\$173	\$(197)	\$(184)

The Company sold the remainder of its New Jersey operating loss carry forwards under a program of the New Jersey Economic Development Authority (NJEDA) in exchange for net proceeds of \$197,000 in 2013 and \$184,000 in 2012. In order to have realized this benefit, the Company applied to the NJEDA and met various requirements for eligibility.

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

	2014	2013	2012
	<b>(in thousands)</b>		
Expected Statutory expense (benefit)	\$1,844	\$(95 )	\$(1,381)
Gain on derivative and amortization of debt discount	(693 )	-	-
Other non-deductible expenses	3	2	1
Change in valuation allowance	(1,031)	30	1317
Sale of New Jersey net operating losses	-	(197)	(189 )
State income taxes, net of federal benefit	50	-	
Federal tax impact of state tax benefit, net	-	63	68
	\$173	\$(197)	\$(184 )

Deferred tax assets included in the Consolidated Balance Sheets as of December 31, 2014 and 2013 consisted of the following:

	2014	2013
	<b>(in thousands)</b>	
<b>Current Assets:</b>		
Reserves and allowances	\$40	\$121
Other	647	161
Total current assets	687	282
<b>Long Term Assets (Liabilities):</b>		
Property, plant and equipment basis difference	245	209
Net operating loss carry forwards	9,068	10,672
Tax credit carry forwards	293	217
Non-employee stock options	682	685
Other	(5 )	(3 )
Total Long Term Assets, net	10,283	11,780
Gross Deferred Tax Asset, net	10,970	12,062
Less Valuation Allowance	(10,970)	(12,062)
Deferred taxes, net	\$-	\$-

The Company evaluates the recoverability of its net deferred tax assets based on its history of operating results, its expectations for the future, and the expiration dates of the net operating loss carry forwards. Based on the preponderance of the evidence, the Company has concluded that it is more likely than not that it will be unable to realize the net deferred tax assets in the immediate future and has established a valuation allowance for all such net deferred tax assets. Accordingly, the Company has provided a valuation allowance of \$11.0 million and \$12.1 million for the years ended December 31, 2014 and 2013, respectively, on its net deferred tax assets. The valuation allowance

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decreased during the year 2014 by \$1.1 million related to pre-tax income for the year ended December 31, 2014.

Operating loss and tax credit carry forwards as of December 31, 2014 were as follows:

	2014	2013
	(in thousands)	
Federal:		
Net operating losses	\$26,602	\$31,308
Research tax credits (expiring through 2025)	168	168
Alternative minimum tax credits (available without expiration)	123	28
State:		
Net operating losses - Tennessee (expiring in 2027)	322	425
Alternative minimum tax assessment - New Jersey (available without expiration)	1	21

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At December 31, 2014, the Company's U.S. federal net operating loss carryforwards will expire as follows:

Year	Net Operating Loss (in thousands)
2020	\$ 5,225
2021	1,157
2022	-
2023	1,232
2024	974
2025	1,850
2026	1,070
2027	308
2028	1,414
2029	3,447
2030	3,455
2031	2,749
2032	3,721
Total	\$ 26,602

The above excludes net operating losses of \$2.4 million which, if realized would be accounted for as additional paid-in capital.

The Company's ability to use net operating loss carry forwards is subject to substantial limitation in future periods under certain provisions of Section 382 of the Internal Revenue Code, which limit the utilization of net operating losses upon a more than 50% change in ownership of the Company's stock that is held by 5% or greater stockholders. The Company examined the application of Section 382 with respect to an ownership change that took place during 2010, as well as the limitation on the application of net operating loss carry forwards. The Company believes that operating losses subsequent to the change date in 2010 (aggregating \$8.5 million) are not subject to Section 382 limitations. The Company has estimated that the annual limitation starting in 2010 aggregates from \$1.0 million to \$2.3 million per year including the effect of amortization of built in gains.

The Company is subject to the provisions of ASC 740-10-25, *Income Taxes* (ASC 740). ASC 740 prescribes a more likely-than-not threshold for the financial statement recognition of uncertain tax positions. ASC 740 clarifies the accounting for income taxes by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. On a quarterly basis, the Company undergoes a process to evaluate whether income tax accruals are in accordance with ASC 740 guidance on uncertain tax positions. For federal purposes, post 1998 tax years remain open to examination as a result of net operating loss carryforwards. The Company is currently open to audit by the appropriate state income taxing authorities for tax years 2010 to 2013.

**15. Lease Commitments**

The Company's commitments and contingencies consisted of operating leases for warehouse and office space and equipment. Future minimum lease payments under non-cancelable operating leases are as follows:

Years Ending December 31,	Amount
2015	\$278,000
2016	418,000
2017	410,000
2018	348,000
2019	318,000
Thereafter	1,168,000
Total	\$2,940,000

Rent expense was \$216,200, \$121,700 and \$66,900 for the years ended December 31, 2014, 2013 and 2012, respectively.

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

On March 2, 2001, the Company became aware of environmental contamination resulting from an unknown heating oil leak at its former manufacturing facility. The Company immediately notified the New Jersey Department of Environmental Protection (NJ DEP) and the local authorities, and hired a contractor to assess the exposure and required clean up. The total estimated costs for the clean-up and remediation is \$836,000, of which approximately \$80,000 remains accrued as of December 31, 2014. Based on information provided to the Company from its environmental consultant and what is known to date, the Company believes the reserve is sufficient for the remaining remediation of the environmental contamination. There is a possibility, however, that the remediation costs may exceed the Company's estimates.

The restricted cash, included in other assets on the Consolidated Balance Sheet of \$54,000 as of December 31, 2014 and 2013 represents a restricted escrow account set up on the requirement of the NJ DEP for the soil remediation work. These funds will be released to the Company upon the DEP approval when the remediation is completed.

On December 19, 2013, we filed a complaint in the United States District Court for the District of Delaware against Mallinckrodt LLC, Mallinckrodt, Inc. and Nuvo Research Inc. (collectively, "Mallinckrodt") seeking a declaration of non-infringement of United States Patent Nos. 8,217,078 and 8,546,450 so that we can bring our generic diclofenac

sodium topical solution 1.5% to market at the earliest possible date under applicable statutory and FDA regulatory provisions.

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

On June 26, 2014, the Company entered into an agreement with Mallinckrodt to settle a declaratory judgment action brought by IGI, concerning the Company's filing of an ANDA with the FDA seeking approval to market a generic version of Pennsaid® (diclofenac sodium topical solution) 1.5% w/w. Under the terms of this agreement, Mallinckrodt granted the Company a non-exclusive license to launch its diclofenac sodium topical solution 1.5% product on March 28, 2015. There was no material impact on the financial statements as a result of the settlement. The Company received tentative approval to sell its diclofenac sodium topical solution 1.5% from the FDA on May 7, 2014.

## **17. Employee Benefits**

The Company has a 401(k) contribution plan, pursuant to which employees may elect to contribute to the plan, in whole percentages, up to 100% of compensation. Employees' contributions are subject to a minimum contribution by participants of 1% of compensation and a maximum contribution of \$17,500 for 2014, \$17,500 for 2013 and \$17,000 for 2012, plus a catch-up contribution of up to \$5,500 for 2014, 2013 and 2012, if a participant qualifies. The Company matches 100% of the first 3% of compensation contributed by participants and 50% of the next 2% of compensation contributed by participants. The Company contribution is in the form of cash, which is vested immediately. The Company has recorded charges to expense related to this plan of approximately \$126,600, \$93,000 and \$71,000 in 2014, 2013 and 2012, respectively.

## **18. 2014 Public Offering**

On June 27, 2014, the Company entered into an underwriting agreement with Roth Capital Partners, LLC and Oppenheimer & Co., as representatives of the several underwriters named therein (the "Underwriters"), relating to the underwritten public offering and sale of up to an aggregate of 4,650,000 shares of the Company's common stock, par value \$0.01 (the "shares"), at a price to the public of \$5.00 per share (the "Offering"). The Company also granted the underwriters a 30-day option to purchase up to an aggregate of 697,500 shares to cover over-allotments, if any.

The Offering was made pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-196543), filed on June 5, 2014 with the Securities and Exchange Commission (the "SEC") and declared effective by the SEC on June 16, 2014, as well as the prospectus supplement describing the terms of the Offering, dated June 27, 2014.

On July 2, 2014, the Company closed the Offering, and after giving effect to the underwriters' exercise of the over-allotment option, the Company sold an aggregate of 5,347,500 shares of common stock in the Offering at a public offering price of \$5.00 per share. The net proceeds of the Offering were approximately \$24.9 million, after deducting underwriting discounts and commissions and other offering expenses paid by the Company.

#### **19. 2012 Private Placement – Former Related Party**

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

In connection with the Offering, the Company also entered into a registration rights agreement (the “*Registration Rights Agreement*”), dated as of December 20, 2012, with the Investor, relating to the registration of the Shares, the Warrants and the shares of common stock issuable upon the exercise of the Warrants, issued in connection with the Offering (the “*Registrable Shares*”). The Registration Rights Agreement provides that the Company will file a “resale” registration statement (the “*Initial Registration Statement*”) covering all of the Registrable Shares within six months of the date of the Registration Rights Agreement and that such Initial Registration Statement shall be declared effective within nine months of the date of the Registration Rights Agreement, subject to certain limitations. Further, the Company has agreed to pay the Investor specified cash payments as partial liquidated damages in the event the Initial Registration Statement is not declared effective by the Securities and Exchange Commission (the “*SEC*”) within the specified timeframe. The Initial Registration Statement was filed with the SEC on May 9, 2013, within six months of the date of the Registration Rights Agreement and became effective on May 13, 2013, within nine months of the date of the Registration Rights Agreement.

#### **20. Asset Purchase Agreements**

##### *Prasco*

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





In consideration for the purchase of the assets pursuant to the Purchase Agreement, the Company paid Prasco \$1.4 million in cash and paid an additional aggregate of \$400,000 upon the occurrence of the milestone events (the “*Milestone Payment*”). The Milestone Payment is secured by a first-priority security interest in the acquired assets under the Purchase Agreement. The transaction is accounted for as a purchase of the product and product rights, and as such the initial payment, milestone payment and related costs to acquire the asset are included as part of product acquisition costs totaling \$1.8 million. The Company is amortizing the costs over fifteen years (approximately \$120,000 per year), the useful life of the acquired product and product rights.

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

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

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

#### AstraZeneca

On September 24, 2014, the Company entered into an Asset Purchase Agreement (the “AZ Purchase Agreement”) with AstraZeneca Pharmaceuticals LP, a Delaware corporation (“AstraZeneca”), pursuant to which the Company acquired all rights, titles and interests of AstraZeneca and its affiliates in Abbreviated New Drug Applications and New Drug Applications associated with eighteen products (collectively the “Purchased Regulatory Approvals”) and certain documents relating thereto (together with the Purchased Regulatory Approvals, the “Purchased Assets”).

In consideration for the purchase of the Purchased Assets, the Company paid AstraZeneca \$500,000 in cash and will be required to pay up to an additional aggregate of \$6,000,000 upon the occurrence of a certain milestone event. The \$6,000,000 is accrued at December 31, 2014 in the payable for product acquisition costs. In addition, the Company has agreed to pay, for each product manufactured by the Company pursuant to a Purchased Regulatory Approval, a royalty on future gross profits from product sales. Notwithstanding the foregoing, at any time prior to December 1, 2015, the Company may satisfy in full its royalty obligations with a single payment of \$3,000,000. The transaction is accounted for as a purchase of the product and product rights, and as such the initial payment, milestone payment and related costs to acquire the asset are included as part of product acquisition costs totaling \$6,910,000. The Company

and will amortize the costs over fifteen years, the useful life of the acquired products and product rights, commencing when the product can be sold.

Valeant

On September 30, 2014, the Company entered into two Asset Purchase Agreements (each, a “Valeant Purchase Agreement” and together, the “Valeant Asset Purchase Agreements”) one with Valeant Pharmaceuticals North America LLC and one with Valeant Pharmaceuticals Luxembourg SARL (together, “Valeant”), pursuant to which the Company acquired all rights, titles and interests of Valeant and their respective affiliates in Abbreviated New Drug Applications and New Drug Applications associated with two products (collectively, the “Valeant Purchased Regulatory Approvals”) and certain documents relating thereto (together with the Valeant Purchased Regulatory Approvals, the “Valeant Purchased Assets”). Pursuant to the terms of the Valeant Asset Purchase Agreements, the Company also acquired the option (each, an “Option” and, collectively, the “Options”) to purchase Abbreviated New Drug Applications and New Drug Applications associated with three additional products (the “Additional Assets”).

In consideration for the purchase of the Valeant Purchased Assets, the Company paid Valeant an aggregate of \$1,500,000 in cash. In consideration for the purchase of the Additional Assets, the Company may exercise any Option, in its sole discretion, and pay \$750,000 for each of two additional products and \$500,000 for one additional product, for a total aggregate of \$2,000,000 if all Options are exercised. The Company purchased the one additional product for \$500,000 on November 18, 2014. The transaction is accounted for as a purchase of the product and product rights, and as such the initial payment and related costs to acquire the Valeant Purchased Assets are included as part of product acquisition costs totaling \$2,048,000. The Company will amortize the costs over fifteen years, the useful life of the acquired product and product rights, commencing when the product can be sold.

**Quarterly Results (Unaudited)**

The following is a summary of certain quarterly financial information for fiscal years 2014 and 2013:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
(in thousands, except per share data)					
Year Ended December 31, 2014					
Total revenues, net	6,853	6,483	6,668	13,736	33,740
Gross profit	2,866	2,903	2,632	8,391	16,792
Operating income (loss)	219	(281 )	(144 )	4,112	3,906
Net income (loss)	167	(345 )	(202 )	5,631	5,251
Net income (loss) attributable to common stockholders	167	(345 )	(202 )	5,631	5,251
Basic income (loss) per share	\$ 0.00	(\$0.01 )	\$0.00	\$ 0.11	\$ 0.11
Diluted income (loss) per share	\$ 0.00	(\$0.01 )	\$0.00	\$ 0.09	\$ 0.09
Year Ended December 31, 2013					
Total revenues, net	3,683	3,820	3,995	6,726	18,224
Gross profit	1,108	1,147	1,311	2,579	6,145
Operating (loss) income	(229 )	(364 )	(42 )	553	(82 )
Net (loss) income	(257 )	(403 )	(95 )	671	(84 )
Net loss attributable to common stockholders	(257 )	(403 )	(95 )	(637 )	(1,392 )
Basic loss per share	(\$0.01 )	(\$0.01 )	\$0.00	(\$0.01 )	(\$0.03 )
Diluted loss per share	(\$0.01 )	(\$0.01 )	\$0.00	(\$0.01 )	(\$0.03 )

IGI LABORATORIES, INC.  
 SCHEDULE II-VALUATION AND QUALIFYING ACCOUNTS  
 (in thousands)

	Balance at Beginning of Year	Additions			Balance at End of Year
		Charged to Costs and Expenses	Charged to Other Accounts	Deductions	
Year Ended December 31, 2013					
Valuation Allowance for Deferred Tax Assets	\$ 12,358	--	--	(296)	) \$ 12,062
Year Ended December 31, 2014					
Fair Value of Convertible Feature of Convertible 3.75% Senior Notes	\$ --	--	43,700	(2,300)	) \$ 41,400
Valuation Allowance for Deferred Tax Assets	\$ 12,062	--	--	(1,092)	) \$ 10,970

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