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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended **December 31, 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	**01-0355758**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
105 Lincoln Ave., Buena, NJ	**08310**
(Address of principal executive offices)	*(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 x

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 x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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 x

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

Smaller reporting company x

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

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*. 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.

5

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: AmericsourceBergen 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, AmerisouceBergen, 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.

Product	Formulation	Presentations	Launch date	Indication
Fluocinolone acetonide 0.01%[(a)]	Solution	60mL	December 2012	Indicated for the relief of the inflammatory pruritic manifestations of corticosteroid-responsive dermatoses
Fluocinolone acetonide 0.025%[(a)]	Ointment	15g, 60g	January 2013	Indicated for the relief of the inflammatory pruritic manifestations of corticosteroid-responsive dermatoses
Fluocinolone acetonide 0.025%[(a)]	Cream	15g, 60g	January 2013	Indicated for the relief of the inflammatory pruritic manifestations of corticosteroid-responsive dermatoses
Fluocinolone acetonide 0.01%[(a)]	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.

Product	Formulation	Presentations	Brand equivalent	Dossier type held by IGI	Overview
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 eleveated serum alkaline phophatase 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. 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.
Mannitol USP 25%	Injectable	50ml (vials and syringes)	Mannitol ®	ANDA	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

10

Product	Formulation	Presentations	Brand equivalent	Dossier type held by IGI	Overview
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 overdosage.
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 vitamine 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 busines