Teligent, Inc.
Form 10-K
March 15, 2016

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, 2015**

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**

Teligent, Inc.

(Formerly 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	The NASDAQ Stock Market

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 ¨

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, 2016, the registrant had 53,005,689 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 25, 2016.

PART I

Item 1. BUSINESS

Our Company

Strategic Overview

Teligent, Inc., or the Company, is a specialty generic pharmaceutical company. Our mission is to become a leader in the specialty generic pharmaceutical market. Under our own label, we currently market and sell generic topical and branded generic injectable pharmaceutical products in the United States and Canada. In the United States we are currently marketing eight generic topical pharmaceutical products and four branded generic pharmaceutical products. Through the completion of an acquisition, we now sell a total of nineteen generic and branded generic injectable products and medical devices in Canada. Generic pharmaceutical products 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 markets. We operate our business under one segment. Effective October 23, 2015, we changed our name from IGI Laboratories, Inc. to Teligent, Inc. On October 26, 2015, our common stock, which was previously listed on the NYSE MKT, began trading on the NASDAQ Global Select Market, under the trading symbol "TLGT." Our office, laboratories and manufacturing facilities are located at 105 Lincoln Avenue, Buena, New Jersey.

Currently, we have two platforms for growth:

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

- Managing our current contract manufacturing and formulation services business.

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 broadened our target product focus from topical pharmaceuticals to include a wider specialty pharmaceutical approach. 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 our existing expertise and capabilities, and broaden our platform for more diversified strategic growth.

As of the date of this report, we have acquired 25 drug products that have been previously approved by the FDA. Our pipeline includes 31 Abbreviated New Drug Applications, or ANDAs filed with the United States Food and Drug Administration, or FDA, for additional pharmaceutical products. In addition, we have four abbreviated new drug submissions, or ANDSs, on file with Health Canada. We have an additional 39 product candidates at various stages of our development pipeline, ten of which are on stability testing. In December 2015, we announced the approval by the FDA of Cefotan® (Cefotan for Injection). This was our first product approved from the portfolio of discontinued and withdrawn new drug applications, or NDAs, and ANDAs that we purchased from Astra Zeneca on September 25, 2014. We have also experienced an increased rate of review by the FDA of applications filed in Generic Drug User Fee Amendments, or GDUFA, Year 3 and Year 4, which began October 1, 2014, and October 1, 2015, respectively. We submitted fifteen topical ANDAs in 2015. We expect to continue to expand our presence in the generic topical 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 fifteen ANDAs in total in 2016 through our internal product development program, and we plan to file at least 8 ANDSs with Health Canada in 2016. We will also seek to license or acquire further products, intellectual property, or pending applications to expand our portfolio.

Teligent Canada. On November 13, 2015, we acquired all of the rights, title and interest in the development, production, marketing, import and distribution of all injectable pharmaceutical products of Alveda Pharmaceuticals Inc., or Alveda, pursuant to two asset purchase agreements, one relating to the acquisition of all of the intellectual property-related assets of Alveda and the other relating to the acquisition of all other assets of Alveda.

In connection with the closing of the acquisition, we formed three subsidiaries: Teligent Luxembourg S.à.r.l., or LuxCo, a private limited company incorporated under the laws of the Grand Duchy of Luxembourg and wholly-owned by the Company; Teligent OÜ, a private limited company incorporated under the laws of Estonia that is wholly-owned by LuxCo; and Teligent Canada Inc., a company incorporated under the laws of the Province of British Columbia that is wholly-owned by LuxCo.

Teligent Canada currently has seven employees, including a general manager of Teligent Canada, located in our offices in Toronto, Canada. Teligent Canada acquired all of the Alveda working capital, including accounts receivable, inventory, accounts payable, and capital assets. In addition, Teligent Canada acquired Alveda's existing customer relations, all contracts necessary to execute the Canadian distribution activities, the existing work force, operational permits, and all intellectual property required to operate the marketing and distributions of products in Canada. Teligent Canada currently markets and distributes nineteen products. We plan to transition these products to distribute them under a Teligent Canada label later this year.

Teligent OÜ. We hired our general manager of Teligent OÜ in the first quarter of 2016. Teligent OÜ will be responsible for the development, enhancement, maintenance, protection and exploitation functions related to the intellectual property-related assets acquired from Alveda. In addition, Teligent OÜ will be responsible for the management of the supply chain function and procurement of products for sale to Teligent Canada. In 2016, we intend to hire additional headcount in Teligent OÜ and secure a quality control laboratory space in preparation to support our Teligent US supply chain management and technical services teams.

Teligent Jersey Limited. On October 5, 2015, we, together with our wholly-owned subsidiary incorporated under the laws of Jersey, or Teligent Jersey, entered into and closed an Asset Purchase Agreement and certain other ancillary agreements with Concordia Pharmaceuticals Inc., S.à.r.l., Barbados Branch, or Concordia, pursuant to which we acquired all rights, title and interests of Concordia in the existing inventory and certain contracts associated with three currently marketed injectable pharmaceutical products (Fortaz®, Zinacef™ , and Zantac® Injection), and Teligent Jersey acquired all rights, title and interests of Concordia in, among other things, certain other contracts, product registrations and books and records associated with those products. In consideration for the purchase of those assets, we paid Concordia an aggregate of $10,100,000 in cash. The transaction is accounted for as a purchase of the product and product rights. In addition, we purchased approximately $1.2 million of inventory related to the three products acquired.

Facility Expansion. With the ongoing expansion activities at our facility of our research and development laboratories, as well as our manufacturing capabilities, 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 continued throughout 2015, and we acquired the building adjacent to our manufacturing facility in August 2015. We have commenced the construction project at 101 Lincoln Avenue, in Buena, New Jersey, which will be the future home to our brand new product development laboratory, in addition to our regulatory affairs, supply chain and corporate services teams. We expect this phase of the project to be

completed in the summer of 2016. We intend to begin the expansion of the existing manufacturing facility at 105 Lincoln Avenue, in Buena, New Jersey in April 2016. This expansion will increase our manufacturing capacity for topical products, and also enable our production of sterile injectable products. In order to begin development, registration and manufacture of some of our sterile injectable and ophthalmic products, we are partnering with contract manufacturing organizations. The current plans consider a total capital outlay of approximately $45 million to complete this project. Upon completion of the site expansion, we may transfer the manufacturing of some of those products back to our Buena, New Jersey facility.

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.

Our Generic Pharmaceutical Business

In September 2010, we leveraged our existing formulation and manufacturing capabilities to begin the Company'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 35 ANDAs to the FDA, of which four have been approved. We submitted fifteen ANDAs in 2015, and expect to file at least fifteen ANDAs in 2016 for topical generic pharmaceutical products.

In December 2012, we launched our first generic topical pharmaceutical products under our own 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%, which received final approval from the FDA in July 2015. 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 January 2016, for the 31 products we have pending at the FDA totals approximately $1.4 billion 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. We also plan to file at least 8 ANDSs with Health Canada in 2016.

As part of our growth strategy, we also seek opportunities to acquire additional products and ANDAs or ANDSs. 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 previously approved ANDAs and NDAs associated with eighteen products, seventeen of which are injectable products and one non-injectable product for pain management. On September 30, 2014, we acquired previously marketed and approved ANDAs 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 March 2015, we completed the purchase of the final two optioned injectable products and their related ANDAs from Valeant.

Our 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 fifteen topical ANDAs for the Teligent portfolio in 2016, 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 2016 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.

Our Financings

On December 22, 2014, we consummated the sale of an aggregate of $143.75 million in principal of our notes, or the Notes, to Deutsche Bank Securities Inc. and J.P. Morgan Securities LLC, as the initial purchasers, including the initial purchasers' exercise of their option to purchase an $18.75 million in principal of Notes. The Notes were sold in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. In connection with the sale of the Notes, we entered into an indenture with Wilmington Trust, National Association, as trustee. 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. 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 and on May 7, 2008, our stockholders approved our name change from IGI, Inc. to IGI Laboratories, Inc. Effective October 23, 2015, we changed our name to Teligent 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.teligent.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 own label, we currently market and sell generic topical and branded generic injectable pharmaceutical products in the United States and Canada. 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. 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 our own label. Currently, we market eight topical products under our own label. We have recently received FDA approvals for lidocaine ointment 5%, which we plan to launch in the first quarter of 2016, and desoximetasone ointment 0.25%, which we plan to launch in the second quarter of 2016. In our topical pipeline, we have 31 ANDAs submitted to the FDA that are awaiting approval, and an additional 39 product candidates in our development pipeline, 10 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 for at least fifteen topical products in 2016 through the ANDA process. Upon regulatory approval, we would market these products under the Teligent 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 January 2016, for the 31 products we have pending at the FDA totals approximately $1.4 billion 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. We are finalizing the planning phase of expanding this facility to increase our topical manufacturing capacity and warehousing capacity to accommodate the expected growth created by the eventual commercial launch of the 31 topical generic pharmaceutical products in our pipeline.

Injectable (I) - As part of the injectable phase of our TICO strategy, on September 24, 2014, we acquired from AstraZeneca previously approved ANDAs and NDAs associated with eighteen products, seventeen 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. We have received FDA approval for our first product in this portfolio, Cefotan® (Cefotetan for Injection), and we are working with our manufacturing partner to launch the product in the first quarter of 2016.

On November 13, 2015, we formed Teligent Canada, and completed the acquisition of Alveda. Teligent Canada currently has seven employees, including a general manager located in our offices in Toronto, Canada. Teligent Canada acquired all of the Alveda working capital, including accounts receivable, inventory, accounts payable, and capital assets. In addition, Teligent Canada acquired Alveda's existing customer relations, all contracts necessary to execute the Canadian distribution activities, the existing work force, operational permits, and all intellectual property required to operate the marketing and distributions of Alveda's products in Canada. Teligent Canada currently markets and distributes nineteen injectable products.

On October 5, 2015, we acquired three currently marketed injectable pharmaceutical products (Fortaz®, Zinacef™ and Zantac® Injection) from Concodia Pharmaceuticals Inc., S.à.r.l., Barbados Branch.

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. In March 2015, we completed the purchase of the final two optioned injectable products and their related ANDA from Valeant.

We intend to leverage our existing topical value chain as we build our injectable generic portfolio. In 2015, we entered into partnerships with contract manufacturing organizations, or CMOs, for the manufacture of some of our products in our portfolio of sterile products. Longer term, we expect to bring much of this production capability in-house.

In 2015, we have performed extensive analysis on the expansion of our existing facility in Buena, New Jersey, and the addition of sterile manufacturing capabilities to our facility. We have completed the concept, design, equipment ordering and construction planning 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 intend to begin construction in April 2016.

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

Complex (C) - We have begun three 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 are researching 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. In addition, we are currently working with a contract research organization to develop a generic equivalent of a pharmaceutical drug product designated for a chronic rare disease. The intent of this opportunity is to provide patients with a lower cost alternative of an approved orphan drug. The Orphan Drug Designation program at the FDA provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons, but are not expected to recover the costs of developing and marketing a treatment drug. 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

Generic Pharmaceutical Business. 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. In October 2015, we acquired and began to sell our first generic injectable products. The injectable products are currently sold under another company's label and will be transitioned to our label in accordance with FDA guidance in 2016. In Canada, we currently market nineteen products in the Alveda label which will be transitioned to the Teligent label in 2016. 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.

For the years ended December 31, 2015, and 2014, 43% and 44% of our total product sales, net, respectively, were to the three large wholesale drug distributors: AmerisourceBergen Corporation, or ABC; Cardinal Health, Inc., or Cardinal; and McKesson Drug Company, or McKesson. ABC accounted for approximately 28% and 42% of our accounts receivable as of December 31, 2015 and 2014, respectively.

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, 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 adverse effect on our revenue, business, financial condition and results of operations. Furthermore, ABC, Cardinal and McKesson have 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 adverse effect on our revenue, business, financial condition and results of operations. For example, we experienced a change in purchasing patterns at ABC in April 2015. We continue to analyze the market for other opportunities to expand our current relationships with other customers, while we continue to seek to diversify our existing portfolio of specialty generic drug products through internal research and development. In addition, we continue to explore business development opportunities to add additional products and /or capabilities to our existing portfolio.

Contract Manufacturing and Development Business. 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. For the year ended December 31, 2015, approximately 86% of our contract services revenue was derived from pharmaceutical customers, as compared to 79% of total contract services revenue for the year ended December 31, 2014. One contract manufacturing customer represented 11% of total revenue for the year ended December 31, 2015, and one of our contract manufacturing services customers represented 13% of total revenue for the year ended December 31, 2014. We do not expect any contract manufacturing or formulation services customers to exceed 10% of revenue for 2016 and beyond.

Concentration of credit risk. In 2015, we had sales to three customers which individually accounted for more than 10% of our total revenue. These customers had sales of $12.3 million, $5.8 million and $5.0 million, respectively, and represented 52% of total revenues in the aggregate. Accounts receivable related to these major customers comprised 83% of all accounts receivable as of December 31, 2015.

In 2014, we had sales to two customers which individually accounted for more than 10% of our 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 these major customers comprised 42% of all accounts receivable as of December 31, 2014.

In 2013, we had sales to three customers which individually accounted for more than 10% of our 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.

Our Products

We recorded net revenue from one product, econazole nitrate cream, which accounted for 45% and 38% of total revenues in 2015 and 2014, respectively. The Company did not have significant revenue from any one product in 2013.

Teligent United States Topical Pharmaceutical Products

Product	Formulation	Presentations	Brand equivalent
Desoximetasone 0.25% (1)	Ointment	15g, 60g, 100g	Topicort®
Diclofenac Sodium 1.5%	Topical Solution	150mL	Pennsaid®
Fluocinolone Acetonide 0.01% (2)	Topical Solution	60mL	Synalar®
Fluocinolone Acetonide 0.025% (2)	Ointment	15g, 60g	Synalar®
Fluocinolone Acetonide 0.025% (2)	Cream	15g, 60g	Synalar®
Fluocinolone Acetonide 0.01% (2)	Cream	15g, 60g	Synalar®
Econazole Nitrate 1%	Cream	15g, 30g, 85g	Spectazole®
Lidocaine 5% (3)	Ointment	35.44g	Xylocaine®
Lidocaine 4%	Topical Solution	50mL	Xylocaine®

(1) ANDA approved by the FDA on February 26, 2016, we expect to launch the product in the second quarter of 2016.
(2) Teligent is the authorized generic to the Synalar NDA held by Medimetriks Pharmaceuticals, Inc.
(3) ANDA approved by the FDA on February 2, 2016, we expect to launch this product in the first quarter of 2016.

Teligent United States Injectable Products

Product	Strength	Formulation	Presentations	Dossier type held by Teligent
Cefotan (Cefotetan) (4)	1g, 2g	Injectable	Vial	NDA
Fortaz (Ceftazidime)	500mg, 1g, 2g, 6g	Injectable	Vial, Twist Vial, Frozen Bag	NDA
Zantac (Ranitidine)	25mg/ml	Injectable	2ml, 6ml, 40ml Vials	NDA
Zinacef (Cefuroxime)	750mg, 1.5g, 7.5g	Injectable	Vial, Twist Vial	NDA

(4) The Prior Approval Supplement approved by the FDA on December 10, 2015. We expect to launch this product in the first quarter of 2016.

Teligent Canada Injectable Products

Product	Strength	Formulation	Presentations	Brand equivalent	Dossier type held by Teligent
Acetylcysteine	2g, 6g	Injectable	10ml and 30 ml vials	Mucomyst® Parvolex®	ANDS
Atropine	0.4 mg, 0.6 mg	Injectable	1 ml vials	N/A	ANDS
Caldolor/Ibuprofen	800 mg	Injectable	8 ml vials	N/A	NDS
Dimenhydrinate	50 mg, 250 mg	Injectable	1 ml ampoule, 5 ml vial	Gravol®	ANDS
Epinephrine	1 mg	Injectable	1 ml ampoule	Adrenalin®	ANDS
Erogonovine Maleate	0.25 mg	Injectable	1 ml ampoule	N/A	ANDS
Furosemide	20 mg	Injectable	2 ml ampoule	Lasix®	ANDS
Irinotecan Hydrochloride	40 mg, 100 mg, 500 mg	Injectable	2 ml, 5 ml, 25 ml vials	Camptosar®	ANDS
Lidocaine 1%	50 mg, 100 mg	Injectable		Xylocaine®	ANDS

			5 ml and 10 ml polyampoule		
Lidocaine 1%	200 mg, 500 mg	Injectable	20 ml and 50 ml vials	Xylocaine®	ANDS
Lidocaine 2%	100 mg, 200 mg	Injectable	5 ml and 10 ml polyampoule	Xylocaine®	ANDS
Lidocaine 2%	400 mg, 1 g	Injectable	20 ml and 50 ml vials	Xylocaine®	ANDS
Lidocaine 2% with epinephrine	400 mg, 1 g	Injectable	20 ml and 50 ml vials	Xylocaine®	ANDS
Methylene Blue	50mg	Injectable	5mL ampoule	N/A	ANDS
Naloxone	0.4mg	Injectable	1mL ampoule	Narcan	ANDS
Piperacillin and Tazobactam	2g, 0.25 g, 3 g, 0.375 g, 4 g, 0.5 g	Injectable	2.25 g, 3.375 g, 4.5 g vials	Tazocin®	ANDS
Sodium Cloride	90 mg	Injectable	10 ml vials	N/A	ANDS
Sterile Water for Injection	100%	Injectable	10 ml polyampoule	N/A	ANDS
Succinylcholine Chloride	200 mg, 400 mg	Injectable	10 ml and 20 ml vials	Quelicin®	ANDS

Teligent United States Other Products

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	**Strength**	**Formulation**	**Presentations**	**Brand equivalent**	**Dossier type held by Teligent**
Ciprofloxacin	0.3%	Ophthalmic Solution	2.5ml, 5ml, 10ml bottles	Ciloxan ®	ANDA
Betaxolol	0.5%	Ophthalmic Solution	5ml, 7.5ml, 15ml bottles	Betopic ®	ANDA
Phytonadione	10mg, 1mg	Injectable	0.5ml, 1ml ampoules; 3cc, 6cc vials	AquaMephyton ®	NDA
Amikacin Sulfate	50mg/ml, 250mg/ml	Injectable	2ml, 4ml vials	Amikacin Sulfate ®	ANDA
Calcitonin Salmon	200IU/ml	Injectable	2ml vials	Miacalcin ®	ANDA
Cefotetan Disodium	20mg/ml	Injectable (bag)	50ml bags	Cefotetan ®	NDA
Clindamycin Phosphate	150mg/ml	Injectable	2ml, 4ml, 6ml, 60ml vials	Cleocin ®	ANDA
Dobutamine HCl	12.5mg/ml	Injectable	20ml, 40ml vials	Dobutamine HCl ®	ANDA
Dopamine HCl	40mg/ml	Injectable	5ml, 10ml (vials and syringes)	Dopamine HCl ®	NDA / ANDA
Dopamine HCl	80mg/ml	Injectable	5ml, 10ml (vials, ampoules, and syringes)	Dopamine HCl ®	NDA / ANDA
Dopamine HCl	160mg/ml	Injectable	5ml (vials and ampoules)	Dopamine HCl ®	NDA / ANDA
Droperidol	2.5mg/ml	Injectable	10ml vials, 2ml and 5ml ampoules, and 2ml syringes	Inapsine ®	ANDA

Furosemide	10mg/ml	Injectable	2ml, 4ml, 8ml, and 10ml vials, 4ml and 10ml syringes	Furosemide ®	ANDA
Mannitol	USP 25%	Injectable	50ml (vials and syringes)	Mannitol ®	ANDA
Meperidine HCl	25mg/ml, 50mg/ml, 75mg/ml, 100mg/ml	Injectable	1ml and 30ml vials, 1ml and 1.5ml ampoules, and 1ml syringes	Demerol ®	ANDA
Midazolam HCl	5mg/ml	Injectable	2ml syringe	Midazolam ®	ANDA
Orphenadrine	30 mg/mL	Injectable	2 mL ampule	Orphenadrine Citrate	ANDA
Edrophonium	10 mg/mL	Injectable	1 mL ampule and 10 mL vial	Enlon®	NDA
MVI-12	N/A	Injectable	10 mL ampules and 5 mL vials	N/A	