Teligent, Inc.
Form 10-K
March 15, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2016
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 ý

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 ý

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 ý 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 ý 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. ý

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 ý
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 ý

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 $306.1 million.

As of March 6, 2017, the registrant had 53,226,382 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 18, 2017.

PART I

Item 1. BUSINESS

Our Company

Strategic Overview

Teligent, Inc., is a specialty generic pharmaceutical company. All references to "Teligent," the "Company," "we," "us," and "our" refer to Teligent, Inc. 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 and generic injectable pharmaceutical products in the United States and Canada. In the United States we are currently marketing 16 generic topical pharmaceutical products and four branded generic pharmaceutical products. Through the completion of an acquisition, we now sell a total of 30 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 principal executive office, laboratories and manufacturing facilities are located at 105 Lincoln Avenue, Buena, New Jersey. We have additional offices located in Iselin, New Jersey, Toronto, Canada, and Tallinn, Estonia.

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 United States Food and Drug Administration, or FDA. Our pipeline includes 34 Abbreviated New Drug Applications, or ANDAs, on file with the FDA, for additional pharmaceutical products. In addition, we have five abbreviated new drug submissions, or ANDSs, on file with Health Canada. We have an additional 34 product candidates at various stages of our development pipeline, ten of which are in 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 AstraZeneca Pharmaceuticals LP, or AstraZeneca, 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 12 topical ANDAs in 2016. 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. We received nine approvals from our internally developed pipeline of topical generic products in 2016. We intend to continue to submit further ANDAs to the FDA and ANDSs to Health Canada in 2017. We will also seek to license or acquire further products, intellectual property, or pending applications to expand our portfolio.

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.

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 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 the Republic 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 nine 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, operational permits, and all intellectual property required to operate the marketing and distribution of products in Canada. Teligent Canada also transitioned a majority of the existing workforce as part of the acquisition. Teligent Canada currently markets and distributes 30 products. Teligent continues to transition these products to distribute them under a Teligent Canada label.

Teligent OÜ. Teligent OÜ currently has five employees, including a general manager of Teligent OÜ. Teligent OÜ is responsible for the development, enhancement, maintenance, protection and exploitation functions related to the intellectual property-related assets acquired from Alveda. In addition, Teligent OÜ is responsible for the management of the supply chain function and procurement of products for sale to Teligent Canada. In 2017, we intend to hire additional employees in Teligent OÜ. We secured a quality control laboratory space to support our Teligent US and Teligent Canada 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. We completed the first phase of our facility expansion in July 2016, with the complete interior renovation of our building at 101 Lincoln Avenue in Buena, New Jersey. This building now houses our new product development laboratory for work on topical and sterile pharmaceuticals. This laboratory integrates our formulation and analytical chemistry teams into one lab, which we expect will increase productivity across the drug development process. This building renovation also houses our regulatory affairs, supply chain and corporate service teams.

We are also progressing with the significant expansion and utilities upgrade of our manufacturing facility at 105 Lincoln Avenue in Buena, New Jersey. The expanded facility will increase our manufacturing capacity for topical products, and will also enable the production of sterile injectable products in both vial and ampule presentations. We are using this facility expansion as an opportunity to upgrade and improve the degree of automation and capacity in our existing topical production suite. The sterile production area is designed around isolator-based technology. The facility will include a versatile vial and ampule filling line capable of four million units per year, with space and critical utilities included in the build-out for a potential future higher-speed filling line. The current plans consider a total capital outlay for 105 Lincoln Avenue of approximately $55 million. We have been partnering with contract manufacturing organizations, or CMOs, for the development, registration and manufacture of some of our sterile injectable and ophthalmic products. Upon completion of the site expansion, we may transfer the manufacture of some

of these injectable products to this facility. We will also use the new sterile production capability to support our internal R&D pipeline of sterile injectable products in vial and ampule presentations.

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.

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. We also have a number of additional product candidates in various stages of development.

Based on Quintiles IMS data, the addressable market, as of January 2017, for the 34 products we have pending at the FDA totals approximately $2.0 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 further ANDSs with Health Canada in 2017.

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 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 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 NDAs 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. We do not expect to record significant revenues from our contract formulation services in 2017 and beyond.

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 two 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 ANDAs on behalf of one of our pharmaceutical partners, both of which were approved in 2016. 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 from the transaction 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 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 we have 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 16 topical products under our own label. We have received FDA approvals for nine topical generic products from our internally developed pipeline in 2016. In our topical pipeline, we have 34 ANDAs submitted to the FDA that are awaiting approval. 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 further regulatory submissions with the FDA in 2017. 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 Quintiles IMS data, the addressable market, as of January 2017, for the 34 products we have pending at the FDA totals approximately $2.0 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 progressing with the significant expansion and utilities upgrade in this facility which will increase our manufacturing capacity for topical products to accommodate the expected growth created by the eventual commercial launch of the 34 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 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, two 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), which we launched in the first quarter of 2016.

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 NDAs from Valeant.

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

On November 13, 2015, we formed Teligent Canada, and completed the acquisition of Alveda. Teligent Canada currently has nine 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, operational permits, and all intellectual property required to operate the marketing and distribution of Alveda's products in Canada. Teligent Canada also transitioned a majority of the existing workforce as part of the acquisition. Teligent Canada currently markets and distributes 30 injectable products.

We intend to leverage our existing topical value chain as we build our injectable generic portfolio. We have 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.

The facility expansion, which began construction activities in the beginning of 2016, will also enable the production of sterile injectable products in both vial and ampule presentations. The sterile production area is designed around forward-thinking isolator-based technology. We have been partnering with CMOs for the development, registration and manufacture of some of our sterile injectable and ophthalmic products. Upon completion of the site expansion, we may transfer the manufacture of some of these products to our Buena, New Jersey facility. We will also use the new sterile production capability to support our internal R&D pipeline of sterile injectable products in vial and ampule presentations.

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, or CRO, 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 commercial production. 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 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. We currently market 30 products in Canada. 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, 2016, and 2015, 41% and 43% 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. As of December 31, 2016, Cardinal accounted for 56% of our accounts receivable, McKesson accounted for 20% of our accounts receivable, and ABC accounted for approximately 11% of our accounts receivable. As of December 31, 2015, ABC represented 28% of our accounts receivable.

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. 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, 2016, approximately 90% of our contract services revenue was derived from pharmaceutical customers, as compared to 86% of total contract services revenue for the year ended December 31, 2015. One contract manufacturing customer represented 10% of total revenue for the year ended December 31, 2016, and one of our contract manufacturing services customers represented 11% of total revenue for the year ended December 31, 2015. We do not expect any contract manufacturing or formulation services customers to exceed 10% of revenue for 2017 and beyond.

Concentration of credit risk. In 2016, we had sales to three customers which individually accounted for more than 10% of our total revenue. These customers had sales of $13.5 million, $8.6 million and $6.8 million, respectively, and represented 43% of total revenues in the aggregate. Accounts receivable related to these major customers comprised 81% of all accounts receivable as of December 31, 2016.

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.

Expansion into foreign operations in the fourth quarter of 2015 has generated net revenues greater than 10% outside of the United States. For the year ended December 31, 2016, domestic net revenues were $56.1 million and foreign net revenues were $10.8 million. As of December 31, 2016, domestic net assets were $120.0 million and foreign assets were $63.2 million.

Our Products

We recorded net revenue from one product, econazole nitrate cream 1%, which accounted for 8% and 45% of total revenues in 2016 and 2015, respectively. We had net revenue from lidocaine ointment 5%, which accounted for 23% of total revenues in 2016, which we launched at the end of the first quarter of 2016.

Teligent United States Topical Pharmaceutical Products

Product	Formulation	Presentations	Brand equivalent	Therapeutic Classification
Desoximetasone 0.25%	Ointment	15g, 60g, 100g	Topicort®	Topical Corticosteroid
Diclofenac Sodium 1.5%	Topical Solution	150mL	Pennsaid®	Topical Anti-inflammatory
Fluocinolone Acetonide 0.01%	Topical Solution	60mL	Synalar®	Topical Corticosteroid
Fluocinolone Acetonide 0.025%	Ointment	15g, 60g	Synalar®	Topical Corticosteroid
Fluocinolone Acetonide 0.025%	Cream	15g, 60g	Synalar®	Topical Corticosteroid
Fluocinolone Acetonide 0.01%	Cream	15g, 60g	Synalar®	Topical Corticosteroid
Econazole Nitrate 1%	Cream	15g, 30g, 85g	Spectazole®	Topical Anti-fungal
Lidocaine USP 5%	Ointment	35.44g	Xylocaine®	Topical Anesthetic
Lidocaine 4%	Topical Solution	50mL	Xylocaine®	Topical Anesthetic
Triamcinolone Acetonide USP 0.1%	Ointment	15g, 80g, 1lb jar	Kenalog®	Topical Corticosteroid
Triamcinolone Acetonide USP 0.025%	Lotion	60ml	Kenalog®	Topical Corticosteroid
Triamcinolone Acetonide USP 0.1%	Lotion	60mL	Kenalog®	Topical Corticosteroid
Clobetasol Propionate 0.05%	Lotion	2oz, 4oz	Clobex®	Topical Corticosteroid
Flurandrenolide USP 0.05%	Ointment	15g, 30g, 60g	Cordran®	Topical Corticosteroid
Clindamycin Phosphate 1%	Topical Solution	30mL, 60mL	Cleocin®	Topical Anti-infective
Nystatin and Triamcinolone Acetonide USP	Ointment	15g, 30g, 60g	Mycolog®	Topical Anti-fungal and Corticosteroid
Triamcinolone Acetonide USP, 0.5% (1)	Ointment	15g	Kenalog®	Topical Corticosteroid
Clobetasol Propionate Gel 0.05% (2)	Gel	15g, 30g, 60g	Temovate®	Topical Corticosteroid

(1) ANDA approved by the FDA on March 3, 2017. We expect to launch the product in the second quarter of 2017.
(2) ANDA approved by the FDA on March 7, 2017. We expect to launch the product in the second quarter of 2017.

8

Teligent United States Injectable Products

Product	Strength	Formulation	Presentations	Dossier type held by Teligent	Therapeutic Classification
Cefotan (Cefotetan) ®	1g, 2g	Injectable	Vial	NDA	Antibacterial for systemic use
Fortaz (Ceftazidime) ®	500mg, 1g, 2g, 6g	Injectable	Vial, Twist Vial, Frozen Bag	NDA	Antibacterial for systemic use
Zantac (Ranitidine) ®	50mg, 150mg, 1g	Injectable	Vials	NDA	Drugs for Peptic Ulcer and gastro-oesophageal related disorders (GORD)
Zinacef (Cefuroxime) ™	750mg, 1.5g, 7.5g	Injectable	Vial, Twist Vial, Frozen Bag	NDA	Antibacterial for systemic use

Teligent Canada Products (1)

Product	Strength	Formulation	Presentations	Brand equivalent	Dossier type held by Teligent	Therapeutic Classification
Acetylcysteine	2 g, 6 g	Injectable	10ml and 30 ml vials	Mucomyst® Parvolex®	ANDS	Antidote
Atropine Injection BP	0.4 mg	Injectable	1 ml ampoules	N/A	DIN	Antimuscarnic, antispasmodic
Atropine Injection BP	0.6 mg	Injectable	1 ml ampoules	N/A	DIN	Antimuscarnic, antispasmodic
Baclofen Injection	0.05 mg	Injectable	1mL ampoules	Lioresal®	ANDS	Muscle Relaxant
Baclofen Injection	10 mg	Injectable	5mL, 20mL ampoules	Lioresal®	ANDS	Muscle Relaxant
Baclofen Injection	40 mg	Injectable	20mL ampoules	Lioresal®	ANDS	Muscle Relaxant
Ibuprofen for Intravenous Infusion	800 mg	Injectable	8 ml vials	Caldolor®	NDS	Nonsteroidal Antiinflammatory Agent
Diazepam Injection USP	10 mg	Injectable	2mL ampoules	Valium®	ANDS	Anxiolytic
Dimenhydrinate Injection USP	50 mg	Injectable	1 ml ampoule	Gravol®	DIN	Antihistamine
Dimenhydrinate Injection USP with preservative	250 mg	Injectable	5 ml vial	Gravol®	DIN	Antihistamine
Epinephrine Injection	1 mg	Injectable	1 ml ampoule	Adrenalin®	DIN	Cardiac Stimulant
Ergonovine Maleate Injection	0.25 mg	Injectable	1 ml ampoule	N/A	ANDS	Oxytocic
Fentanyl Citrate Injection USP	100 mcg	Injectable	2mL ampoule	Sublimaze®	ANDS	Opiate Anesthetic
Furosemide Injection USP	20 mg	Injectable	2 ml ampoule	Lasix®	ANDS	Diuretic
Gentamicin Injection USP	80 mg	Injectable	2mL ampoule	Garamycin®	NDS	Antibiotic

Irinotecan Hydrochloride	40 mg, 100 mg, 500 mg	Injectable	2 ml, 5 ml, 25 ml vials	Camptosar®	ANDS	Antineoplastic agent
Lidocaine Hydrochloride Injection (1% Preservative Free)	50 mg, 100 mg	Injectable	5 ml and 10 ml polyampoule	Xylocaine®	DIN	Local Anesthetic

Lidocaine Hydrochloride Injection with Preservative (1%)	200 mg, 500 mg	Injectable	20 ml and 50 ml vials	Xylocaine®	DIN	Local Anesthetic
Lidocaine Hydrochloride Injection (2% Preservative Free)	100 mg, 200 mg	Injectable	5 ml and 10 ml polyampoule	Xylocaine®	DIN	Local Anesthetic
Lidocaine Hydrochloride Injection with Preservative (2%)	400 mg, 1 g	Injectable	20 ml and 50 ml vials	Xylocaine®	DIN	Local Anesthetic
Lidocaine 2% and Epinephrine 1:100,000 Injection	400 mg, 1 g	Injectable	20 ml and 50 ml vials	Xylocaine®	DIN	Local Anesthetic
Lidocaine Hydrochloride Topical Solution USP 4%	2000 mg	Topical Solution	50mL	Xylocaine®	DIN	Topical Anesthetic
Lidocaine Ointment USP 5%	1750 mg	Ointment	35g	Xylocaine®	DIN	Topical Anesthetic
Methylene Blue Injection USP	50 mg	Injectable	5mL ampoule	N/A	DIN	Antidote
Naloxone Hydrochloride Injection USP	0.4 mg	Injectable	1mL ampoule	Narcan®	ANDS	Opiate Antagonist
Piperacillin and Tazobactam for Injection	2 g, 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	Antibacterial for systemic use
Sodium Chloride Injection USP 0.9%	90 mg	Injectable	10 ml vials	N/A	DIN	Diluent
Sterile Water for Injection USP	100%	Injectable	10 ml polyampoule	N/A	DIN	Diluent
Succinylcholine Chloride Injection USP	200 mg, 400 mg	Injectable	10 ml and 20 ml vials	Quelicin®	DIN	Muscle Relaxant

(1) Table does not include Euflexxa®, which is not owned by Teligent Canada but is distributed and sold by Teligent Canada.

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	Therapeutic Classification
Ciprofloxacin	0.3%	Ophthalmic Solution	2.5ml, 5ml, 10ml bottles	Ciloxan ®	ANDA	Antibacterial for systemic use
Betaxolol	0.5%	Ophthalmic Solution	5ml, 7.5ml, 15ml bottles	Betopic ®	ANDA	Beta Blocking Agent
Phytonadione	10mg, 1mg	Injectable	0.5ml, 1ml ampoules; 3cc, 6cc vials	AquaMephyton ®	NDA	Hemostatic
Amikacin Sulfate	50mg/ml, 250mg/ml	Injectable	2ml, 4ml vials	Amikacin Sulfate	ANDA	Antibacterial for systemic use
Calcitonin Salmon	200IU/ml	Injectable	2ml vials	Miacalcin ®	ANDA	Anti-parathyroid Agent
Cefotetan Disodium	20mg/ml	Injectable (bag)	50ml bags	Cefotan ®	NDA	Antibacterial for systemic use
Cefotetan	10mg/ml	Injectable	2ml vials	Cefotan ®	NDA	Antibacterial for systemic use
Clindamycin Phosphate	150mg/ml	Injectable	2ml, 4ml, 6ml, 60ml vials	Cleocin ®	ANDA	Antibacterial for systemic use
Dobutamine HCl	12.5mg/ml	Injectable	20ml, 40ml vials	Dobutamine HCl	ANDA	Cardiac Stimulant
Dopamine HCl	40mg/ml	Injectable	5ml, 10ml (vials and syringes)	Dopamine HCl	NDA / ANDA	Cardiac Stimulant
Dopamine HCl	80mg/ml	Injectable	5ml, 10ml (vials, ampoules, and syringes)	Dopamine HCI	NDA / ANDA	Cardiac Stimulant
Dopamine HCl	160mg/ml	Injectable	5ml (vials and ampoules)	Dopamine HCl	NDA / ANDA	Cardiac Stimulant
Droperidol	2.5mg/ml	Injectable	10ml vials, 2ml and 5ml ampoules, and 2ml syringes	Inapsine ®	ANDA	Anti-Psychotic
Furosemide	10mg/ml	Injectable	2ml, 4ml, 8ml, and 10ml vials, 4ml and 10ml syringes	Furosemide	ANDA	Diuretic
Mannitol	USP 25%	Injectable	50ml (vials and syringes)	Mannitol	ANDA	Diuretic
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	Systemic analgesic
Midazolam HCl	5mg/ml	Injectable	2ml syringe	Midazolam	ANDA	Sedative
Orphenadrine	30 mg/mL	Injectable	2 mL ampule	Orphenadrine Citrate	NDA	Muscle Relaxant
Edrophonium	10 mg/mL	Injectable	1 mL ampule and 10 mL vial	Enlon®	NDA	Acetylcholinesterase inhibitor
MVI-12	N/A	Injectable	10 mL ampules and 5 mL vials	N/A	NDA	Systemic multivitamin
Naloxone HCl		Injectable		N/A	ANDA	Opiate Antagonist

	0.4 mg/mL, 1 mg/mL		1 mL 5 mLand 10 mL vials			
Naloxone HCl (preservative free)	0.4 mg/mL	Injectable	1 mL vials	N/A	ANDA	Opiate Antagonist
Pancuronium	1 mg/ml, 2mg/ml	Injectable	10ml vials, 2mg/ml (vials, ampoules, and syringes)	N/A	ANDA	General anesthesia
Tobramycin Sulfate	10 mg/mL, 40 mg/mL	Injectable	2 mLand 35 mL vials	N/A	ANDA	Antibacterial for systemic use
Nalbuphine	10 mg/mL and 20 mg/mL	Injectable	1 mL and 10 mL vials	Nubain®	ANDA	Systemic analgesic

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. The APIs and other materials and supplies used in our pharmaceutical manufacturing operations are generally available and purchased from many different U.S. and non-U.S. suppliers. However, in some cases, the raw materials used to manufacture pharmaceutical products are available only from a single supplier. Even when more than one supplier exists, we may choose, and in some cases have chosen, only to list one supplier in our applications submitted to the FDA. Any change in a supplier not previously approved must then be submitted through a formal approval process with the FDA. No raw materials or components suppliers represented 10% or more of our purchases in 2016, 2015 or 2014.

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 is led by our Chief Scientific Officer, Stephen Richardson, who joined the Teligent team in October 2015. The R&D team consists of 33 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 injectable products and topical products in a wide range of dosage forms, including simple solutions through complex creams. All ANDA topical development is conducted in-house except for bioequivalence testing, which is performed by a contract research organization.

We have been steadily increasing our investment in R&D as we believe that R&D is the future of the Company. We incurred $17.1, $13.2, and $6.9 million in R&D expenses in 2016, 2015, and 2014, respectively. We expect to increase our R&D spending in 2017 to approximately 24% to 27% of revenue in 2017 in order to expand our ANDA submissions and pipeline. As the business continues to grow over the next three to five years, we expect research and development costs as a percentage of revenue to decline.

Product Development and Government Regulation

United States

Prescription pharmaceutical products in the U.S. are generally marketed as either brand or generic drugs. Brand products are usually marketed under brand names through marketing programs that are designed to generate physician and consumer loyalty. Brand products generally are patent protected, which provides a period of market exclusivity during which time they are sold with little or no competition for the compound, although there typically are other participants in the therapeutic area. Additionally, brand products may benefit from other periods of non-patent market exclusivity. Exclusivity normally provides brand products with the ability to maintain their profitability for relatively long periods of time and brand products typically continue to play a significant role in the market due to physician and consumer loyalties after the end of patent protection or other market exclusivities.

Generic pharmaceutical products are the pharmaceutical and therapeutic equivalents of the brand product, also known as the reference listed drug, or RLD. A reference listed brand drug is an approved drug product listed in the FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, popularly known as the Orange Book. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, provides that generic drugs may enter the market after the approval of an ANDA. An ANDA approval requires that bioequivalence to the reference listed drug be demonstrated and also requires that any patents on the corresponding reference listed drug be expired, invalidated, non-infringed and/or any other relevant market exclusivity periods related to the reference listed drug be expired as well. Generic drugs are bioequivalent to their reference brand name

counterparts. Accordingly, generic products provide a safe, effective and cost-efficient alternative to users of these reference brand products. Branded generic pharmaceutical products are generic products in that they are approved for marketing under an ANDA, but they may be more responsive to promotion efforts generally used to promote branded pharmaceutical products. Growth in the generic pharmaceutical industry has been, and will continue to be, driven by the increased market acceptance of generic drugs, as well as the number of brand drugs for which patent terms and/or other market exclusivities have expired.

We obtain new generic products primarily through internal product development. Additionally, we license or co-develop products through arrangements with other companies. All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. Information to support the bioequivalence of generic drug products or the safety and effectiveness of new drug products for their intended use is also required to be submitted. There are generally two types of applications used for obtaining FDA approval of new products:

- New Drug Application — An NDA is filed when approval is sought to market a newly developed branded product and, in certain instances, for a new dosage form, a new delivery system or a new indication for a previously approved drug.

- Abbreviated New Drug Application — An ANDA is filed when approval is sought to market a generic equivalent of a drug product previously approved under an NDA and listed in the FDA's Orange Book or for a new dosage strength for a drug previously approved under an ANDA.

The ANDA development process is generally less time-consuming and complex than the NDA development process. It typically does not require new preclinical and clinical studies, because it relies on the studies establishing safety and efficacy conducted for the RLD previously approved through the NDA process. The ANDA process, however, does typically require one or more bioequivalence studies to show that the ANDA drug is bioequivalent to the previously approved reference listed brand drug. Bioequivalence studies compare the bioavailability of the proposed drug product with that of the RLD product containing the same active ingredient. Bioavailability is a measure of the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. Thus, a demonstration of bioequivalence confirms the absence of a significant difference between the proposed product and the reference listed brand drug in terms of the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action when administered at the same molar dose under similar conditions.

Generic products are generally introduced to the marketplace at the expiration of patent protection for the brand product or at the end of a period of non-patent market exclusivity. However, if an ANDA applicant files an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed in the Orange Book with respect to a reference drug product, the applicant may be able to market the generic equivalent prior to the expiration of patent protection for the brand product. Such patent certification is commonly referred to as a Paragraph IV certification. If the holder of the NDA sues, claiming infringement or invalidation, within 45 days of notification by the applicant, the FDA may not approve the ANDA application until the earlier of the rendering of a court decision favorable to the ANDA applicant or the expiration of 30 months. An ANDA applicant that is first to file a Paragraph IV certification is eligible for a period of generic marketing exclusivity. This exclusivity, which under certain circumstances may be required to be shared with other ANDA sponsors that have made Paragraph IV certifications, lasts for 180 days, during which the FDA cannot grant final approval to other ANDA applications for a generic equivalent to the same reference drug.

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent market exclusivity, during which the FDA cannot approve an application for a generic version product. If the reference drug is a new chemical entity, the FDA may not accept an ANDA for a generic product for up to five years following approval of the NDA for the new chemical entity. If it is not a new chemical entity, but the holder of the NDA conducted clinical trials essential to approval of the NDA or a supplement thereto, the FDA may not approve an ANDA for a reference NDA product before the expiration of three years. Certain other periods of exclusivity may be available if the RLD is indicated for treatment of a rare disease or the sponsor conducts pediatric studies in accordance with FDA requirements.

Supplemental ANDAs are required for approval of various types of changes to an approved application and these supplements may be under review for six months or more. In addition, certain types of changes may only be approved once new bioequivalence studies are conducted or other requirements are satisfied.

An additional requirement for FDA approval of NDAs and ANDAs is that our manufacturing procedures and operations conform to FDA requirements and guidelines, generally referred to as current Good Manufacturing Practices, or cGMPs. The requirements for FDA approval encompass all aspects of the production process, including validation and recordkeeping, the standards around which are continuously changing and evolving.

Facilities, procedures, operations and/or testing of products are subject to periodic inspection by the FDA, the U.S. Drug Enforcement Administration, or DEA, and other authorities. In addition, the FDA conducts pre-approval and

post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with cGMP and other FDA regulations. Our suppliers are subject to similar regulations and periodic inspections.

In 2012, the U.S. Food and Drug Administration Safety and Innovation Act, or the FDASIA, was enacted into law. FDASIA is intended to enhance the safety and security of the U.S. drug supply chain by holding all drug manufacturers supplying products to the U.S. to the same FDA inspection standards and schedules. Specifically, prior to the passage of FDASIA, U.S. law required U.S. based manufacturers to be inspected by the FDA every two years but remained silent with respect to foreign manufacturers, causing some foreign manufacturers to go as many as nine years without a routine FDA cGMP inspection, according to the Government Accountability Office.

FDASIA also included GDUFA, a novel user fee program to provide FDA with approximately $1.5 billion in total user fees through 2018 focused on three key aims:

- Safety – Ensure that industry participants, foreign or domestic, are held to consistent quality standards and are inspected with parity using a risk-based approach.

- Access – Expedite the availability of generic drugs by bringing greater predictability to the review times for abbreviated new drug applications, amendments and supplements and improving timeliness in the review process.

- Transparency – Enhance FDA's visibility into the complex global supply environment by requiring the identification of facilities involved in the manufacture of generic drugs and associated APIs, and improve FDA's communications and feedback with industry.

Under GDUFA, 70% of the total fees are being derived from facility fees paid by Finished Dosage Form manufacturers and API facilities listed in pending or approved generic drug applications. The remaining 30% of the total fees are being derived from application fees, including generic drug application fees, prior approval supplement fees and fees for certain types of Drug Master Files, or DMFs.

Canada

In Canada, the registration process for approval of all generic pharmaceuticals has two tracks that proceed in parallel. The first track of the process involves an examination of the proposed generic product by Health Canada, the federal department responsible for national public health, to ensure that the quality, safety and efficacy of the proposed generic product meets Canadian standards and bioequivalence requirements. The second track concerns patent rights of the brand drug owner. Companies may submit an application called an abbreviated new drug submission, or ANDS, to Health Canada that compares the proposed generic drug to another drug marketed in Canada under a Notice of Compliance, or NOC, issued to a first person. When Health Canada is satisfied that the generic pharmaceutical product described in the ANDS satisfies the statutory requirements, it issues an NOC for that product for the uses specified in the ANDS, subject to any court order that may be made in the second track of the approval process.

The second track of the approval process is governed by the Patented Medicines NOC Regulations, or the Regulations. The owner or exclusive licensee of patents relating to the brand drug for which it has an NOC may have established a list of patents administered by Health Canada that enumerates all the patents claiming the medicinal ingredient, formulation, dosage form or the use of the medicinal ingredient. It is possible that even though the patent for the API may have expired, the originator may have other patents on the list which relate to new forms of the API, a formulation or additional uses. Most brand name drugs have an associated patent list containing one or more unexpired patents claiming the medicinal ingredient itself or a use of the medicinal ingredient (a claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms). In its ANDS, a generic applicant must make at least one of the statutory allegations with respect to each patent on the patent list, for example, alleging that the patent is invalid or would not be infringed and explaining the basis for that allegation. In conjunction with filing its ANDS, the generic applicant is required to serve the originator a Notice of Allegation, or NOA, which gives a detailed statement of the factual and legal basis for its allegations in the ANDS. The originator may commence a court application within 45 days after it has been served with the NOA, if it takes the position that the allegations are not justified. When the application is filed in court and served on Health Canada, Health Canada may not issue an NOC until the earlier of the determination by the court after a hearing or the expiration of 24 months from the commencement of the generic drug application. The period may be shortened or lengthened by the court in certain circumstances. An NOC can be obtained for a generic product only if the generic respondent is successful in dismissing the application under the Regulations in court. The legal costs incurred in connection with the application could be substantial.

Section C.08.004.1 of the Canadian Food and Drug Regulations is the so-called data protection provision, and the current version of this section applies in respect of all drugs for which an NOC was issued on or after June 17, 2006.

A subsequent applicant for approval to market a drug for which an NOC has already been issued does not need to perform duplicate clinical trials similar to those conducted by the first NOC holder, but is permitted to demonstrate safety and efficacy by submitting data demonstrating that its formulation is bioequivalent to the formulation that was issued for the first NOC. The first party to obtain an NOC for a drug will have an eight-year period of exclusivity starting from the date it received its NOC based on those clinical data. A subsequent applicant for approval that seeks to establish safety and efficacy by comparing its product to the product that received the first NOC will not be able to file its own application until six years after the issuance of the first NOC. The Minister of Health will not be permitted to issue an NOC to that applicant until eight years after the issuance of the first NOC — this additional two-year period will correspond in most cases to the 24-month automatic stay under the Regulations. If the first person provides the Minister with the description and results of clinical trials relating to the use of the drug in pediatric populations, it will be entitled to an extra six months of data protection. A drug is only entitled to data protection so long as it is being marketed in Canada.

Facilities, procedures, operations and/or testing of products are subject to periodic inspection by Health Canada. In addition, Health Canada conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems are in compliance

with the Good Manufacturing Practices in Canada, Drug Establishment Licensing requirements and other provisions of the Regulations. Competitors are subject to similar regulations and inspections.

The federal government, provinces and territories in Canada operate drug benefit programs through which eligible recipients receive drugs through public funding; these drugs are listed on provincial or territorial Drug Benefit Formularies (each, a "Formulary"). Eligible recipients include First Nations and Inuit clients, seniors, persons on social assistance, low-income earners, and those with certain specified conditions or diseases. Formulary listings are also used by private payors to reimburse generic products. To be listed in a Formulary, drug products must have received an NOC from Health Canada and must comply with each jurisdiction's individual review process.

The primary regulatory approval for pharmaceutical manufacturers, distributors and importers selling pharmaceuticals to be marketed in Canada is the issuance of an establishment license, or EL. An EL is issued to a Canadian facility once Health Canada has approved the facilities in which the pharmaceuticals are manufactured, distributed or imported. A key requirement for EL-issuance is compliance with the Good Manufacturing Practices as set out by Health Canada. For pharmaceuticals that are imported into Canada, the license for the Canadian importing facility must list all foreign sites at which imported pharmaceuticals, and their active ingredients, are manufactured and tested. To be listed on our EL, all our foreign sites must demonstrate compliance with relevant Good Manufacturing Practices recognized by Health Canada.

Sales and Marketing

We manufacture, sell, distribute and market our prescription drug products to national chain drug stores and drug wholesalers and distributors and group purchasing organizations, or GPOs, in the United States and Canada. This commercialization infrastructure includes satisfying our state, provincial, territorial, or national licensing requirements, implementing procedures with our third-party logistics partners, and maintaining appropriate sales order to cash administrative processes and a manager of national accounts to manage our sales.

Competition

In our generic topical prescription drug business, we face competition 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 five dominant companies in the topical generic drug market are: Sandoz (the generic pharmaceutical division of Novartis AG), Taro Pharmaceutical Industries, Ltd., Perrigo Company, Teva Pharmaceutical Industries, Ltd. and Akorn, Inc. Collectively, these five competitors control approximately 58% of the generic topical market by value based on Quintiles IMS data from December 2016. We believe the concentrated nature of the topical generic drug market creates an opportunity for us to 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.

In our generic injectable prescription drug business, we also face competition 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 dominant competitors in the injectable generic drug market. The 7 dominant companies in the injectable generic drug market in the United States consist of Hospira, Inc. (a subsidiary of Pfizer, Inc.), Fresenius Kabi USA, Sandoz (the generic pharmaceutical division of Novartis AG), Grifols USA, LLC, West-Ward (a subsidiary of Hikma Pharmaceuticals PLC), Mylan, Inc., and Winthrop (a subsidiary of Sanofi-Aventis U.S. LLC.). Collectively, these seven competitors control approximately 63% of the generic injectable market by value based on Quintiles IMS data from December 2016. In Canada, we face competition from largely the same firms as in the United States as well as certain Canada-only firms. The Canadian generic injectable market is dominated by Sandoz (the generic pharmaceutical division of Novartis AG), Pfizer Injectables and Fresenius Kabi

Canada.

Our generic injectable strategy is focused on injectable products with limited competition, and products that have a history of lack of supply, or instability in the supply chain, where we can add value and leverage on our ability to be a reliable supplier to the marketplace. We believe the concentrated nature of some molecules within the injectable generic drug market, and history of lack of supply of certain molecules in the marketplace, create opportunities for us that we believe will enable us 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 14 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

The Company's executive administrative offices are located in Buena, New Jersey, in two facilities of approximately 33,000 square feet built on 8.44 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. We are in the process of expanding our facility to total approximately 103,000 square feet. 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.

We also lease an additional 11,000 square feet of warehouse space in Vineland, New Jersey.

The Company also leases approximately 7,500 square feet of corporate office space in Iselin, New Jersey, approximately 4,000 square feet of office space in Toronto, Canada and approximately 2,605 square feet of office and laboratory space in Tallinn, Estonia.

Employees

On December 31, 2016, we had a total of 153 full-time employees, including nine full-time employees in Canada and five full-time employees in Estonia. In addition, as the need arises, we occasionally utilize short-term, part-time employees who are paid on an hourly basis. We also 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.

With the exception of 2015, our expenses exceeded our revenue in each of the last 12 years, and no net income has been available to common stockholders during each of these years. As of December 31, 2016, our stockholders' equity was $56.7 million and we had an accumulated deficit of $44.9 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. Three of our customers accounted for 43% of our revenue for the year ended December 31, 2016, and three of our customers accounted for 52% of our revenue for the year ended December 31, 2015. 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.

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. While we continue to diversify our product portfolio, one of our products accounted for 8% and 38% of our revenue for the years ended December 31, 2016 and 2015, respectively. Any material adverse developments, including increased competition, loss of customers, pricing pressures 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.

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.

Furthermore, in the current political climate in which drug prices are a focus of the current administration, Congress, government and private payors, and the public more broadly, we cannot predict whether new legislative, regulatory, or other measures related to drug pricing may be enacted. If enacted, such drug pricing measures could have an impact on our drug prices or our gross margins from product sales, which could significantly and adversely impact our financial condition and cash flows.

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 identical 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. In addition, the FDA has continued to shorten the review and response time to certain ANDAs, as a result of their guidelines established under GDUFA. If this trend continues, and the FDA is successful in reducing the current backlog of unapproved ANDAs, currently pending approval at the FDA, competitors could potentially enter the markets in which we compete more quickly. 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.

Our strategy depends on our ability to successfully develop and launch new pharmaceutical products ahead of our competitors.

Our continued growth is dependent upon our ability to develop and commercialize products in a timely manner. We may encounter delays in testing and manufacturing new pharmaceutical products, submitting applications for regulatory approval, receiving approval from the relevant authorities and commercializing new products. This process is costly and time-consuming. Delays at any stage could prevent us from successfully launching new products ahead of our competitors and could have a material adverse effect on our business, financial condition and results of operations.

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 "authorized 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, when feasible (given that significant new clinical data must be provided to FDA in a "switch" application and some drug products are not safe enough to be sold over-the-counter). Our competitors, which include major multinational corporations, are consolidating in both the branded and generics industries, 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.

Our business and operations have experienced rapid growth, and if we do not appropriately manage any future growth, our business will be adversely affected.

We have experienced, and are continuing to experience, rapid growth over the last several years, and additional growth through acquisitions is possible in the future. Such growth has put significant demands on our management and infrastructure. Our success will depend in part upon our ability to manage this growth effectively. As we continue to grow, we must improve our operational, financial and management controls and our reporting systems and procedures. We must ensure that our policies and procedures evolve to reflect our current operations. We must also continue to effectively manage existing employees and to hire, train and manage new employees as needed. Any failure to expand these areas and implement appropriate procedures and controls in an efficient manner and at a pace consistent with our business objectives could have a material adverse effect on our business, financial condition and

results of operations.

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

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.

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 that have been pre-approved by FDA for use in the manufacture of our products. In this type of limited-supplier situation, increased prices, rationing and/or shortages can occur. In response to the situation, we try to identify alternative materials or suppliers for such raw materials and finished goods like containers and closures. However, 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.

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 a potentially 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.

We depend on a limited number of suppliers for API. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers must usually be approved through a Prior Approval Supplement by the FDA.

We maintain several single-source supplier relationships, either because alternative sources are not available or because 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 relevant 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.

Incidents related to hazardous materials could materially adversely affect our reputation, business, financial condition, operating results and cash flows.

There are portions of our operations that require the controlled use of hazardous materials. Although we are diligent in designing and implementing safety procedures to comply with the standards prescribed by federal, state, and local regulations, the risk of

accidental contamination of property or injury to individuals from these materials cannot be completely eliminated. In the event of such an incident, we could be liable for any damages that result, which could materially adversely affect our reputation, business, financial condition, operating results and cash flows.

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

In the United States, 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 $0.9 million as of December 31, 2016, and remaining costs accrued at December 31, 2016 totaled $0.1 million. 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.

In Canada, we and our suppliers of raw materials are also subject to regulation under Hazardous Products Act, Controlled Products Regulations, Consumer Product Safety Act. Canadian Environmental Protection Act and other current and potential future federal, provincial/territorial 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, provincial/territorial 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.

Future events, such as new information, changes in existing environmental laws or their interpretation, and more vigorous enforcement policies of federal, provincial/territorial 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 Abbreviated

New Drug Application, or 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 (approved under a New Drug Application, or NDA), 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, or current Good Manufacturing Practices, 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.

We are subject to extensive government regulation by Health Canada and other federal, state provincial/territorial 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 Canadian agencies, including Health Canada, as well as by several state and local agencies in localities where our products are stored, distributed or sold. In addition, we market certain of our products in accordance with standards set by organizations, such as the United States Pharmacopeial Convention, or USP, and the British Pharmacopeia, or BP, scientific nonprofit organizations that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. Adherence to USP and BP published drug standards are prescribed by the Food and Drug Regulations.

Health Canada regulates the testing, manufacture, labeling, marketing and sale of pharmaceutical products. Approval by Health Canada is required before any new drug, including any new generic drug, may be marketed or sold in Canada. In order to receive approval from Health Canada for our product candidates that are generic versions of brand-name drugs, we intend to use the ANDS, or Drug Identification Number Application, or DINA, routes, which requires us to demonstrate to Health Canada 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 (approved under a New Drug Submission or NDS or Drug Identification Number Application, or DINA), meaning that there is no significant difference between the drugs in their rate and extent of absorption in the body. However, if Health Canada determines that an ANDS or DINA 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 Health Canada approval through the ANDS or DINA process, the labeling claims and marketing statements that we can make for our generic drugs are generally limited to the claims approved by Health Canada 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 an importer and distributor of pharmaceutical products, we must also comply with cGMPs, or current Good Manufacturing Practices, which include requirements related to production processes, quality control and assurance and recordkeeping. Our facilities and procedures and those of our suppliers are subject to periodic inspection by Health Canada 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 non-compliance ratings, a delay or suspension in manufacturing operations. 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, and revoking of licenses, any of which could significantly and adversely affect supplies of our products.

Our global operations expose us to certain risks, including challenges associated with political and economic instability, major hostilities and acts of terrorism.

We are a global company with operations outside of the United States. We face numerous risks inherent in conducting business internationally, including terrorist acts, acts of war, political unrest, public health concerns, labor disputes and national disasters. Such events may lead to economic and political uncertainties and contribute to global economic instability. We may not be successful in developing and implementing policies and strategies to address the foregoing events in a timely and effective manner. Consequently, the occurrence of one or more of the foregoing events could have a material adverse impact on our business, operating results and financial condition, including loss of sales or customers.

Violations of cGMP and other government regulations could have a material adverse effect on our reputation, business, financial condition and results of operations.

All facilities and manufacturing techniques used to manufacture pharmaceutical products for clinical use or for commercial sale in the United States and other Teligent markets must be operated in conformity with cGMP regulations as required by the FDA and other regulatory bodies. Our suppliers' facilities are subject to scheduled periodic regulatory and customer inspections to ensure compliance with cGMP and other requirements applicable to such products. A finding that we or one or more of our suppliers had materially violated these requirements could result in one or more regulatory sanctions, loss of a customer contract, disqualification of data for client submissions to regulatory authorities and a mandated closing of our suppliers' facilities, which in turn could have a material adverse effect on our reputation, business, financial condition, operating results and cash flows.

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. 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.

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.

We are currently in the process of expanding our manufacturing facilities. Any delays in the expansion process or in the receipt of certain regulatory approvals in connection therewith could have a material adverse effect on our business and results of operations.

We are in the process of expanding and upgrading our existing manufacturing facilities in Buena, New Jersey. Upon the completion of this expansion, we intend to transfer the manufacture of certain sterile injectable, for which we currently rely on CMOs, to this facility. Any delays in the expansion process could increase the overall cost of the

expansion and could force us to postpone the planned transfer of our manufacturing to this facility. In addition, any delays or denials of the regulatory approvals needed to begin manufacturing products at this facility could have a material adverse effect on our business.

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.

Our policies regarding returns, allowances and chargebacks, failure to supply penalties and marketing programs adopted by wholesalers may reduce revenues in future fiscal periods.

We, like other generic drug manufacturers, have agreements with customers allowing chargebacks, product returns, administrative fees, failure to supply penalties and other rebates. Under many of these arrangements, we may match lower prices offered to customers by competitors. If we choose to lower our prices, we generally give the customer a credit on the products that the customer is holding in inventory, which could reduce sales revenue and gross margin for the period the credit is provided. Under many of these arrangements, we may have failure to supply penalties, which in the event we are unable to supply a certain product and are unable to meet the needs of our customers, we may incur failure to supply penalties which may be significant. Like our competitors, we also give credits for chargebacks to wholesalers with whom we have contracts for their sales to hospitals, group purchasing organizations, pharmacies or other customers. A chargeback is the difference between the price at which we invoice the wholesaler and the price that the wholesaler’s end-customer pays for a product. Although we establish reserves based on prior experience and our best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that our reserves are adequate or that actual product returns, allowances, and chargebacks will not exceed our estimates. As we continue to experience the consolidation of our customers, which may result in changes to previous patterns of ordering and/or pricing of our products, this could disrupt our established methodologies for calculating our provisions for chargebacks and other accruals.

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, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH 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, including methods to investigate the comparative effectiveness of different products used for similar indications, 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 and Health Canada, 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 our reputation or the reputation of the product. 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 and reputational harm 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.

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, CROs 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 to us 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. In addition, if third party fraud or other recordkeeping problems are discovered after our products are approved for marketing, any government investigations or findings could result in any products that incorporated those fraudulent results having their regulatory approvals withdrawn.

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 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.

The trademark applications we have filed or may file may not result in trademark registrations, which would result in lesser protections for our brands.

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.

Significant balances of intangible assets, including goodwill, are subject to impairment testing and may result in impairment charges, which may materially and adversely affect our results of operations and financial condition.

A significant amount of our total assets is related to goodwill and intangible assets. As of December 31, 2016 the value of our goodwill and intangible assets net of accumulated amortization was $52.9 million. Goodwill and other intangible assets are tested for impairment annually when events occur or circumstances change that could potentially reduce the fair value of the reporting unit or intangible asset. Impairment testing compares the fair value of the reporting unit or intangible asset to its carrying amount. Any future goodwill or other intangible asset impairment, if any, would be recorded in operating income and could have a material adverse effect on our results of operations and financial condition.

We may not be able to fully realize the expected benefits from the acquisition of certain products and/or companies.

Our recent acquisition of certain products and a company 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 and in markets outside of the United States.

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. Enforcement actions and 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 government enforcement action or litigation, whether or not successful, may damage our reputation. Furthermore, we are likely to incur substantial expense in defending these actions and lawsuits, and the time demands of such enforcement actions and 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.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

In addition, we rely on complex information technology systems, including Internet-based systems, to support our supply chain processes as well as internal and external communications. The size and complexity of our systems make them potentially vulnerable to breakdown or interruption, whether due to computer viruses or other causes that may result in the loss of key information or the impairment of production and other supply chain processes. Such disruptions and breaches of security could adversely affect our business.

Compliance with ongoing post-marketing obligations for our approved ANDAs, NDAs, NDSs, and ANDSs may uncover new safety information that could give rise to a product recall, updated warnings, or other regulatory actions that could have an adverse impact on our business.

After the FDA or Health Canada approves a drug for marketing under an NDA, ANDA, NDS, or ANDS, the product's sponsor must comply with several post-marketing obligations that continue until the product is discontinued. These post-marking obligations include the prompt reporting of serious adverse events to the agency, the submission of product-specific annual reports that include changes in the distribution, manufacturing, and labeling information, and notification when a drug product is found to have significant deviations from its approved manufacturing specifications (among others). Our ongoing compliance with these types of mandatory reporting requirements could result in additional requests for information from the FDA or Health Canada and, depending on the scope of a potential product issue that the FDA or Health Canada may decide to pursue, potentially also result in a request from the agency to conduct a product recall or to strengthen warnings and/or revise other label information about the product. Any of these post-marketing regulatory actions could materially affect our sales and, therefore, they have the potential to adversely affect our business, financial condition, results of operations and cash flows.

Economic conditions could severely impact us.

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

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

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

of product components, thereby impairing our ability to manufacture on schedule and at commercially reasonable costs.

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

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

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

certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

If we are unable to satisfy regulatory requirements relating to internal controls, our stock price could suffer.

Section 404 of the Sarbanes-Oxley Act of 2002 requires companies to conduct a comprehensive evaluation of the effectiveness of their internal control over financial reporting. At the end of each fiscal year, we must perform an evaluation of our internal control over financial reporting, include in our annual report the results of the evaluation and have our external auditors also publicly attest to the effectiveness of our internal control over financial reporting. If material weaknesses are found in our internal controls in the future, if we fail to complete future evaluations on time or if our external auditors cannot attest to the effectiveness of our internal control over financial reporting, we could fail to meet our regulatory reporting requirements and be subject to regulatory scrutiny and a loss of public confidence in our internal controls, which could have an adverse effect on our stock price.

Currency fluctuations and changes in exchange rates could adversely affect our business, financial condition, results of operations, cash flows, and/or common stock price.

Although we report our financial results in U.S. Dollars, a portion of our revenues and other liabilities and our costs are denominated in non-U.S. currencies, including the Euro and Canadian Dollar. Our results of operations and, in some cases, cash flows, have in the past been and may in the future be adversely affected by certain movements in currency exchange rates. The occurrence of any of the above risks could cause a material adverse effect on our business, financial condition, results of operations, cash flows, and/or share price.

The Company is exposed to market risk from fluctuations in currency exchange rates.

The Company operates in multiple jurisdictions denominated in currencies of the local jurisdiction. Additionally, the Company
may enter into acquisition, licensing, borrowing or other financial transactions that may give rise to currency exposure. Since
the Company cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange
rates could negatively affect the Company’s results of operations, financial position and cash flows.

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

As of December 31, 2016, we had federal net operating loss carry forwards, or NOLs, of approximately $34.6 million which expire from 2020 through 2035. 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 $15.3 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.

We are currently involved in antitrust litigation related to our pricing practices.

Complaints have been filed against us in each of the U.S. District Court for the District of New Jersey and the U.S. District Court for the Eastern District of Pennsylvania alleging violations of various provisions of federal and state antitrust laws in connection with the sale of our antifungal skin cream Econazole Nitrate 1% product. While we intend to vigorously defend our position in connection with both lawsuits, the outcome of the litigation could result in serious fines being levied on us, along with harm to our reputation. Any negative outcome from this or any other investigation related to our pricing could have a material adverse effect on our business, financial condition and results of operations.

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 year ended December 31, 2016, the average daily trading volume of our common stock on the NASDAQ Global Select Market was approximately 299,310 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, 2016 and December 31, 2015, and our management concluded that our disclosure controls and procedures were effective as of such times. The year ended December 31, 2014 was the first year in which we were 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 $4.46 in the first quarter of 2016 and a high of $12.05 in the first quarter of 2015. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

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

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 NASDAQ Global Select Market, our common stock could be delisted and our liquidity and stock price could suffer.

Our common stock is listed on the NASDAQ Global Select Market, 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 NASDAQ Global Select Market, 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, or 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.

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, 2016, our total consolidated indebtedness was $143.75 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

The Company’s executive administrative offices are located in Buena, New Jersey, in two facilities totaling approximately 33,000 square feet built on 8.44 acres of land in 1995, which we own. One of those facilities is used for production, product development, marketing and warehousing for our own generic prescription pharmaceutical products and pharmaceutical, cosmeceutical and cosmetic products. In July 2016, the Company completed the first phase of the facility expansion in the Buena, New Jersey location. The facility now houses our new product development laboratory for work on topical and sterile pharmaceuticals. The other facility is currently being expanded to increase our manufacturing capacity for topical products, and will also enable the production of sterile injectable products in both vial and ampule presentations. We lease an additional 11,000 square feet of warehouse space in Vineland, New Jersey, lease approximately 7,500 square feet of corporate office space in Iselin, New Jersey, and lease approximately 4,000 square feet of office space in Toronto, Canada. The Company also leases approximately 2,605 square feet of office and laboratory space in Tallinn, Estonia.

Item 3. LEGAL 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, or 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 was $889,000, of which approximately $123,000 remains accrued as of December 31, 2016. 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 $122,000 as of December 31, 2016 and $124,000 as of December 31, 2015, 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 NJ 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., which we collectively refer to as 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. On January 10, 2014, Mallinckrodt filed an answer and counterclaim alleging that we infringed the patents at issue. On June 26, 2014, we entered into a settlement agreement with Mallinckrodt, pursuant to which Mallinckrodt granted us a non-exclusive license to launch our diclofenac sodium topical solution 1.5% product on March 28, 2015. There was no material impact on our financial statements as a result of the settlement. We received approval to sell our diclofenac sodium topical solution 1.5% from the FDA in July 2015.

On May 21, 2015, Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc., which we collectively refer to as Horizon, filed a complaint in the United States District Court for the District of New Jersey against the Company alleging infringement of certain United States patents based upon our submission to the FDA of an Abbreviated New Drug Application, or ANDA seeking FDA approval to market diclofenac topical solution 2% w/w before the expiration of the patents asserted in the complaint. On June 30, 2015, August 11, 2015, September 17, 2015, October 27, 2015 and February 5, 2016, Horizon filed additional complaints in the United States District Court for the District of New Jersey against the Company alleging infringement of other of its United States patents in relation to the Company's submission of the same ANDA. On July 21, 2015, September 11, 2015, October 6, 2015, October 21, 2015, December 17, 2015 and March 17, 2016, the Company filed answers, affirmative defenses and counterclaims with respect to the complaints filed by Horizon. In those filings, the Company asserted that the patents alleged to be infringed in the complaints filed by Horizon are invalid and not infringed by us. On April 27, 2016, Horizon and the Company filed a stipulation of dismissal to dismiss the cases. The court entered an order dismissing the cases on May 2, 2016. On May 9, 2016, Horizon and the Company entered into a settlement agreement. Under the settlement agreement, the Company obtained a license to market diclofenac topical solution 2% no later than January 10, 2029 or earlier in certain circumstances, including the resolution by settlement or court decision of other third party litigation involving diclofenac topical solution 2% or the market entry by other third party generic versions of diclofenac topical solution 2%. At this time, the Company cannot estimate if or when any of those earlier events might occur. No consideration was exchanged as part of the settlement. The Company has not recorded accruals related to this case and has not yet received final approval.

On December 4, 2015, Galderma Laboratories, L.P. and Galderma S.A., which we collectively refer to as Galderma, filed a complaint in the United States District Court for the Northern District of Texas against us alleging infringement of United States Patent No. 6,106,848 based upon our submission to the FDA of an ANDA seeking FDA approval to

market clobetasol propionate lotion 0.05% before the expiration patent asserted in the complaint. On January 5, 2016, Galderma and the Company entered into a Settlement and License Agreement, the terms of which are confidential. On January 22, 2016, the case was dismissed with prejudice.

From December 20, 2016 to January 26, 2017, eight putative class action antitrust lawsuits were filed against the Company, along with co-defendants including Taro Pharmaceuticals U.S.A., Inc., Perrigo New York Inc., Fougera Pharmaceuticals Inc., and Sandoz, Inc. The actions are currently pending in the District of New Jersey and Eastern District of Pennsylvania, and a consolidation motion is currently pending before the Judicial Panel on Multidistrict Litigation.

The class plaintiffs seek to represent nationwide or state classes consisting of persons who directly purchased, indirectly purchased or reimbursed patients for the purchase of generic econazole from any of the defendants from June 1, 2014 (or later in some complaints) until the time the defendants' allegedly unlawful conduct ceased or will cease.

The plaintiffs allege a conspiracy to fix prices for generic econazole, in violation of federal antitrust laws or state antitrust, consumer protection, and other laws. Plaintiffs seek treble damages for alleged price overcharges for generic econazole during the alleged

period of conspiracy, and the indirect purchaser class plaintiffs seek injunctive relief against Teligent.

All of these cases are in their initial stages. The parties are negotiating briefing schedules for motions to dismiss, which will be filed after the Judicial Panel on Multidistrict Litigation determines an appropriate forum. Due to the early stage of these cases, we are unable to form a judgment at this time as to whether an unfavorable outcome is either probable or remote or to provide an estimate of the amount or range of potential loss. We intend to vigorously defend against these claims.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

We transferred the listing of our common stock from the NYSE MKT to the NASDAQ Global Select Market. Our common stock ceased trading on the NYSE MKT under the symbol "IG" at the close of business on October 23, 2015 and began trading on the NASDAQ Global Select Market under the symbol "TLGT" on October 26, 2015.

The following table sets forth, for the periods indicated, the high and low sales prices for our common stock, as reported by the NYSE MKT and the NASDAQ Global Select Market, as applicable.

	Common Stock	
	High	Low
2016		
First Quarter	8.88	4.46
Second Quarter	7.39	4.79
Third Quarter	8.66	6.96
Fourth Quarter	7.99	5.75
2015		
First Quarter	12.05	7.75
Second Quarter	9.40	4.75
Third Quarter	8.98	6.13
Fourth Quarter	9.18	5.90

Stockholders

As of March 6, 2017, there were approximately 378 stockholders of record of our 53,226,382 outstanding shares of common stock.

Dividends

We have not paid cash dividends to our stockholders since inception and we do not plan to pay cash dividends in the foreseeable future. We currently intend to retain earnings, if any, to finance the growth of the Company.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Performance Graph
Comparison of Cumulative Total Return among Teligent, Inc.,
the S&P 500 Index and the Dow Jones - US Health Care Index

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,				
	2016	2015	2014	2013	2012
(In thousands, except per share data)					
Revenues	$66,881	$44,250	$33,740	$18,224	$8,563
Gross profit	34,687	21,315	16,972	6,145	2,776
Operating income (loss)	2,542	(3,192)	3,906	(82)	(3,136)
Interest and other non-operating income (expense)	(14,240)	9,895	1,518	(199)	(975)
Pretax income (loss)	(11,698)	6,703	5,424	(281)	(4,111)
Income tax provision (benefit)	287	35	173	(197)	(184)
Net income (loss)	$(11,985)	$6,668	$5,251	$(84)	$(3,927)
Preferred stock dividend	—	—	—	(1,308)	—
Net income (loss) attributable to common stockholders	$(11,985)	$6,668	$5,251	$(1,392)	(3,927)
Weighted average shares outstanding:					
Basic	53,078	52,873	49,818	43,518	39,786
Diluted	53,078	67,112	64,207	43,518	39,786
PER SHARE:					
Net income (loss):					
Basic	(0.23)	0.13	0.11	(0.03)	(0.10)
Diluted	(0.23)	(0.07)	0.09	(0.03)	(0.10)
Share Price: High	8.88	12.05	11.28	3.39	1.48
Low	4.46	4.75	2.93	1.00	0.94
BALANCE SHEET DATA:					
Current assets	$103,296	$116,801	$177,218	$10,558	$6,139
Net property, plant & equipment	26,215	8,706	3,262	2,623	2,691
Total assets	183,226	184,762	197,078	15,427	9,427
Current liabilities	14,963	10,768	13,002	5,221	1,976
Long-term obligations, less current installments	111,596	107,235	144,942	3,015	1,024
Shareholders' equity	56,667	66,759	39,134	7,191	6,427
CASH FLOW DATA:					
Cash provided by (used in) operating activities	$1,098	$(15,513)	$(3,891)	$(618)	$(2,373)
Cash used in investing activities	(21,972)	(53,068)	(3,792)	(2,113)	(342)
Cash provided by (used in) financing activities	(10)	(3,111)	164,465	2,296	2,337
Increase/(Decrease) in cash and cash equivalents	(20,884)	(71,692)	156,782	(435)	(378)

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

Teligent, Inc. is a specialty generic pharmaceutical company. All references to "Teligent," the "Company," "we," "us," and "our" refer to Teligent, Inc. 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 16 generic topical pharmaceutical products and four branded generic pharmaceutical products. Through the completion of an acquisition, we now sell a total of 30 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 principal executive office, laboratories and manufacturing facilities are located at 105 Lincoln Avenue, Buena, New Jersey. We have additional offices located in Iselin, New Jersey, Toronto, Canada, and Tallinn, Estonia.

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 United States Food and Drug Administration, or FDA. Our pipeline includes 34 Abbreviated New Drug Applications, or ANDAs filed with the FDA, for additional pharmaceutical products. In addition, we have five abbreviated new drug submissions, or ANDSs, on file with Health Canada. We have an additional 34 product candidates at various stages of our development pipeline, ten of which are in 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 AstraZeneca 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 12 topical ANDAs in 2016. 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. We received nine approvals from our internally developed pipeline of topical general products in 2016. We intend to continue to submit further ANDAs to the FDA and ANDSs to Health Canada in 2017. We will also seek to license or acquire further products, intellectual property, or pending applications to expand our portfolio.

Effective October 26, 2015, we transferred the listing of our common stock from the NYSE MKT to the NASDAQ Global Select Market. Our common stock ceased trading on the NYSE MKT under the symbol “IG” at the close of business on October 23, 2015 and began trading on the NASDAQ Global Select Market under the symbol “TLGT” on October 26, 2015.

On November 13, 2015, we acquired all of the rights, title and interest in the development, production, marketing, import and distribution of all 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.

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 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.

Results of Operations

Fiscal Year 2016 Compared to Fiscal Year 2015

We had a net loss of $12.0 million, or $0.23 per share, in 2016 compared to net income of $6.7 million, or $0.13 per share, in 2015.

Revenues (in thousands):

	Year Ended December 31,		Increase/(Decrease)	
Components of Revenue:	2016	2015	$	%
Product sales, net	$65,904	$43,497	$ 22,407	52 %
Research and development services and other income	977	753	224	30 %
Total Revenues	$66,881	$44,250	$ 22,631	51 %

The increase in product sales for the year ended December 31, 2016 as compared to the same period in 2015 was primarily due to the increased revenue from our own generic pharmaceutical product line and our entry into the specialty generic injectable market in the U.S. and Canada. In addition, our contract manufacturing revenues increased over the same period in the prior year, primarily due to our acquisition of two new customers, one in the fourth quarter of 2015 and one in the first six months of 2016, for which we manufactured one of our generic topical products in a private label, offset by a slight decline in purchase orders. We do not expect revenue from these two contract manufacturing customers in 2017 and beyond.

Research and development services and other income will not be consistent and will vary, from period to period, depending on the required timeline of each development project and/or agreement.

Costs and expenses (in thousands):

	Year Ended December 31,		Increase/(Decrease)	
	2016	2015	$	%
Cost of revenues	32,194	$22,935	$ 9,259	40 %
Selling, general and administrative	15,005	11,336	3,669	32 %
Product development and research	17,140	13,171	3,969	30 %
Totals costs and expenditures	$64,339	$47,442	$ 16,897	36 %

Cost of revenues increased for the year ended December 31, 2016 as compared to the same period in 2015 as a result of the increase in total revenue. Cost of revenues decreased as a percentage of total revenue to 48% for the year ended December 31, 2016 as compared to 52% for the same period in 2015. The decrease in cost of revenue as a percentage of sales was primarily due to the increased revenue from our own generic pharmaceutical product line driven by new product launches and our entry in to the specialty generic injectable market. Sales related to our own label products generally have lower cost of revenues percentages than our contract manufacturing product revenues; however, sales to one new contract manufacturing customer, where we sold more of our generic products in a private label, did reduce cost of revenues as a percentage of sales. In addition, our costs of revenue include the provision for the write-down of inventory of $1.4 million. This write-down includes the write-down of the inventory step up in basis in the amount of $0.5 million. The inventory step-up was initially recorded in connection with our acquisition of Alveda Pharmaceuticals, Inc. in November 2015. Our research and development income results primarily from services rendered under contractual agreements and, therefore, cost of revenues as a percentage of our research and development income is relatively low. Consistent with our strategy, we expect cost of revenues as a percentage of total revenue to decline over time.

Selling, general and administrative expenses for the year ended December 31, 2016 increased by $3.7 million as compared to the same period in 2015. In 2016, there were increases of $2.3 million in amortization expense related to assets acquired in the fourth quarter of 2015, $1.3 million in expenses related to our Canadian operations, $0.8 million in salaries and related costs, $0.5 million in expenses related to our Estonia operations, $0.4 million in recruiting fees, other corporate expenses of $0.3 million, bad debt expense of $0.3 million, $0.1 million from the issuance of stock-based compensation related to options and restricted stock, $0.1 million in conferences and seminars and $0.1 million in board of directors fees, offset by a decrease of $2.5 million in professional fees.

Product development and research expenses for the year ended December 31, 2016 increased by $4.0 million as compared to the same period in 2015. Consistent with our strategy to expand our portfolio of generic prescription pharmaceutical products, we increased headcount, which resulted in an increase of $1.8 million in salaries and related costs, $1.4 million in exhibit and pilot batch costs, $0.7 million in clinical studies, $0.5 million in expenses related to Canadian operations, $0.4 million in stock based compensation related to options and restricted stock and $0.3 million in overhead costs. These were partially offset by decreases in consulting fees of $0.9 million, $0.1 million in fees related to Generic Drug User Fee Act, or GDUFA, and the associated filing of our applications with the FDA and technology license fees of $0.1 million.

Interest and Other Expense, net (in thousands):

	Year Ended December 31,		Increase/(Decrease)	
	2016	2015	$	%
Interest and other expense, net	$(13,304)	$(13,358)	$54	— %
Foreign exchange (loss) / gain	$(936)	$109	$(1,045)	100 %
Change in the fair value of derivative liability	$—	$23,144	$(23,144)	(100)%

Interest expense increased for the year ended December 31, 2016 as compared to the same period in 2015. The increase is related to the interest expense, amortization of debt discount and amortization of debt issuance costs of the Notes (see Note 6), partially offset by capitalized interest related to our facility expansion. Foreign exchange loss of $0.9 million was recorded for the year ended December 31, 2016, primarily related to the foreign currency translation of our intercompany loans denominated in U.S. dollars to our foreign subsidiaries. These loans are to be repaid in November 2022. Depending on the changes in foreign currency exchange rates, we will continue to record a non-cash gain or loss on translation for the remainder of the term of these loans. Due to the nature of this transaction, there is no

economic benefit to the Company to hedge this transaction. During the year ended December 31, 2015, we recorded a $23.1 million change in the fair value of the derivative liability as a result of the change in the fair value of our derivative liability, caused primarily by the decrease in the price of our common stock. Due to the approval of the sufficient shares at the Company's annual shareholder meeting, the liability for the embedded derivative was reclassified to equity on May 20, 2015, and as such there is no change in the fair value of the derivative liability recorded for the year ended December 31, 2016.

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

	Year Ended December 31,		Increase/(Decrease)	
	2016	2015	$	%
Net (loss) income attributable to common stockholders	$(11,985)	$6,668	$(18,653)	(280)%
Basic (loss) income per share	$(0.23)	$0.13	$(0.36)	(277)%
Diluted loss per share	$(0.23)	$(0.07)	$(0.16)	229 %

Net loss for the year ended December 31, 2016 was $12.0 million as compared to net income of $6.7 million for the year ended December 31, 2015. The decrease is due to increases in costs and expenses in 2016, foreign currency exchange loss of $0.9 million, and the absence of change in the fair value of the derivative liability that occurred in 2015 in the amount of $23.1 million, partially offset by increases in revenues in 2016.

Fiscal Year 2015 Compared to Fiscal Year 2014

We had net income of $6.7 million in 2015 compared to net income of $5.3 million in 2014. Net income attributable to common stockholders was $6.7 million, or $0.13 per share in 2015, and net income applicable to common stockholders was $5.3 million, or $0.11 per share, in 2014:

Revenues (in thousands):

	Year Ended December 31,		Increase/(Decrease)	
Components of Revenue:	2015	2014	$	%
Product sales, net	$43,497	$32,104	$ 11,393	35 %
Research and development services and other income	753	1,636	(883)	(54)%
Total Revenues	$44,250	$33,740	$ 10,510	31 %

The increase in product sales for the year ended December 31, 2015 as compared to the same period in 2014 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 an additional Company label product in July 2015, the purchase of three commercialized injectable products in October 2015 and the launch of two additional Company label products in June 2014. There was a decrease in product sales in our contract services business to three of our pharmaceutical customers and one cosmetic customer, which was only partially offset by increased sales to three 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. 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)	
	2015	2014	$	%
Cost of revenues	$22,935	$16,948	$ 5,987	35 %
Selling, general and administrative	11,336	5,976	5,360	90 %
Product development and research	13,171	6,910	6,261	91 %
Totals costs and expenditures	$47,442	$29,834	$ 17,608	59 %

Cost of revenues increased for the year ended December 31, 2015 as compared to the same period in 2014 as a result of the increase in total revenue. Cost of revenues as a percentage of total revenue was 52% for the year ended December 31, 2015 as compared to 50% for 2014. During 2015, approximately 86% of our revenue from contract and formulation services came from pharmaceutical customers as compared to 79% in 2014. Our research and development income results primarily from services rendered under contractual agreements and, therefore, cost of revenues as a percentage of our research and development income is relatively low. Consistent with our strategy, we expect cost of revenues as a percentage of total revenue to decline over time.

Selling, general and administrative expenses for the year ended December 31, 2015 increased by $5.4 million as compared to the same period in 2014. During the fourth quarter of 2015, the Company recorded acquisition related costs in the amount of $2.3 million. In addition, in 2015 there were increases of $1.1 million from the issuance of stock-based compensation related to options and restricted stock, other corporate expenses of $0.5 million, professional fees of $0.4 million, amortization of product acquired in 2015 of $0.4 million, expenses related to Canadian operations of $0.2 million, travel-related costs of $0.2 million, website expenses of $0.1 million, overhead costs of $0.1 million, recruiting and human resources expenses of $0.1 million, contributions of $0.1 million and stockholder relations expense of $44,000 during the year ended December 31, 2016 as compared to the same period in 2015. These increases were partially offset by a decrease of $47,000 in salaries and related costs.

Product development and research expenses for the year ended December 31, 2015 increased by $6.3 million as compared to the same period in 2014. Consistent with our strategy to expand our portfolio of generic prescription pharmaceutical products, we increased headcount, including hiring our Chief Scientific Officer in October of 2015, which resulted in an increase of $0.8 million in salaries and related costs; we increased spending on clinical studies by $2.7 million, costs related to our exhibit batches by $1.0 million, contract research by $0.9 million, professional fees by $0.3 million, $0.2 million in expenses related to Canadian operations, stock based compensation related to options and restricted stock of $0.2 million, consulting fees by $0.1 million and overhead costs by $0.1 million. In addition, fees related to GDUFA, and the associated filing of our applications with the FDA, increased by $0.1 million.

Interest and Other Expense, net (in thousands):

	Year Ended December 31,		Increase/(Decrease)	
	2015	2014	$	%
Interest and other expense, net	$(13,358)	$(782)	$(12,576)	1,608 %
Foreign exchange gain	$109	$—	$109	100 %
Change in the fair value of derivative liability	$23,144	$2,300	$20,844	906 %

Interest expense increased for the year ended December 31, 2015 as compared to the same period in 2014, primarily due to the inclusion in 2015 of approximately $12.8 million 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). Gain on foreign exchange in 2015 resulted from the change in exchange rates applied to funds due from Teligent Canada at December 31, 2015. We also recorded a $23.1 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 2015.

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

	Year Ended December 31,		Increase/(Decrease)	
	2015	2014	$	%
Net income attributable to common stockholders	$6,668	$5,251	$1,417	27 %
Basic income per share	$0.13	$0.11	$0.02	18 %
Diluted (loss) income per share	$(0.07)	$0.09	$(0.16)	(178)%

Net income for the year ended December 31, 2015 increased as compared to the year ended December 31, 2014 due to the change in the fair value of the derivative liability, partially offset by the increase in revenues and the increase in

costs and expenses noted above.

Liquidity and Capital Resources

Our principal sources of liquidity were cash and cash equivalents of approximately $66.0 million at December 31, 2016 and cash from operations. The Company terminated its $10 million credit facility with General Electric Capital Corporation, as agent, and GE Capital Bank and certain other institutions, as lenders, in February 2016. We had working capital of $88.3 million at December 31, 2016. 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 2018.

On December 10, 2014, we entered into a purchase agreement, pursuant to which we agreed to sell 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. We received net proceeds of approximately $139 million, after expenses of $4.8 million, upon completion of the transaction. The sale was completed on December 16, 2014. See Note 6.

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. 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 provided $1.1 million of cash during the year ended December 31, 2016 compared to $15.5 million and $3.9 million of cash used during the years ended December 31, 2015 and 2014, respectively. The cash provided for the year ended December 31, 2016 was mostly due to the collection of the Canadian goods and services tax, or GST, and the harmonized sales tax, or HST, of $5.2 million, in addition to other changes in operating assets and liabilities, offset by $7.6 million of interest expense related to our Notes. The use of cash for the year ended December 31, 2015 was a result of $5.2 million paid related to Canadian GST and HST and interest expense in the amount of $6.7 million related to our Notes. In connection with the acquisition of Alveda, we paid $2.2 million in acquisition costs. The remaining use of cash was primarily a result of the $3.8 million in changes in operating assets and liabilities, which included a $6.0 million payment related to the AstraZeneca assets acquired in September of 2015, offset by the net income for the year. 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.

Our investing activities used $22.0 million during the year ended December 31, 2016 compared to $53.1 million of cash used in the year ended December 31, 2015 and $3.8 million of cash used in the year ended December 31, 2014. The funds used for the year ended December 31, 2016 included $18.6 million in capital expenditures, for which the majority were for the facility expansion in Buena, as well as expenditures for the Estonian lab, and $3.4 million in product acquisition costs including Sebela and the buyout of the royalty stream related to AstraZeneca (See Note 16). The funds used for the year ended December 31, 2015 included $35.4 million in cash paid to acquire the assets of Alveda in November 2015. We completed the acquisition of five products, which used $11.7 million in cash in 2015. We also used $6.0 million for the purchase of capital expenditures related to additional scientific and manufacturing equipment and costs related to the planning phase of our expansion. The funds used during the year ended December 31, 2014 were for the purchase of products (see Note 7 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.

Our financing activities used $10,000 of cash during the year ended December 31, 2016 compared to $3.1 million of cash used in financing activities in the year ended December 31, 2015 and $164.5 million of cash provided by financing activities in the year ended December 31, 2014. The cash used during the year ended December 31, 2016 was mainly $70,000 of principal payments on capital lease obligations offset by $96,000 in proceeds from the exercise of common stock warrants and options. The cash used during the year ended December 31, 2015 in the amount of $3.1 million was used to pay down debt. 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 net proceeds from the exercise of common stock warrants and options.

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 a warehouse in Vineland, New Jersey, office space in Iselin, New Jersey, office space in Toronto, Canada and office and laboratory space in Tallinn, Estonia. Our remaining obligations under these leases are summarized in the table below.

As of December 31, 2016, our principal outstanding debt obligation related to our Notes is a total of $143.75 million and are due in December of 2019.

	Payments Due by Period (in thousands)				
Contractual Obligations	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Convertible Senior Notes	$143,750	$—	$143,750	$—	$—
Capital Lease	—	—	—	—	—
Operating Lease	2,987	548	879	818	742
Total	$146,737	$548	$144,629	$818	$742

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 carrying amounts of cash and cash equivalents, trade receivables, restricted cash, notes payable, accounts payable, capital leases and other accrued liabilities at December 31, 2016 approximate their fair value for all periods presented. 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 the aggregate of $143.75 million in principal notes issued on December 16, 2014, to Deutsche Bank Securities Inc. and J.P. Morgan Securities LLC, as the initial purchasers, or the Notes, 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 Notes with the option and then considering the value of the Notes without the option. The difference is the fair

value of the embedded derivatives. The embedded 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.

On May 20, 2015, the Company received approval to increase its authorized shares sufficiently to allow for the conversion of the Notes into equity at the annual shareholders meeting. Therefore, the derivative liability of $18.3 million was reclassified into stockholders equity. The Company recorded a change in the fair value of the derivative liability through May 20, 2015 of $23.1 million for the year ended December 31, 2015. On May 20, 2015, the Company reclassified the fair value of the derivative liability into stockholders equity due to the approval of sufficient shares. Based on the closing price of the Company's common stock as of December 31, 2016, the net carrying value of the Notes was approximately $111.4 million compared to their face value of $143.75 million as of December 31, 2016. 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.

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 90-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 pharmaceutical products, sales of manufactured product for its customers included in product sales, and research and product development services and other 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, net, include Company Product Sales and Contract Manufacturing Sales.

Company Product Sales: The Company records revenue from Company 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 is customary in the pharmaceutical industry, the Company's gross product sales from Company 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, or 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 estimates 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, subsequent actual payment experience 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, net in the Company's Condensed Consolidated Statement of Operations.

Research and Development Services and Other 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. Other types of revenue include royalty or licensing revenue, and would be recognized based upon the contractual agreement upon completion of the earnings process.

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, or 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 was the embedded convertible option of its Notes issued December 16, 2014 (see Note 6), which has been recorded as a liability at fair value until May 20, 2015, and was 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). Due to the approval of the sufficient shares at the Company’s annual shareholder meeting, the liability for the embedded derivative was reclassified to equity on May 20, 2015. The Company has no derivatives at December 31, 2016 and December 31, 2015.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America, or 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 December 2016, the FASB issued ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers". The update provides users with classification guidance on thirteen specific areas of correction or improvement topics as follows: 1) Loan Guarantee Fees, 2) Contract Costs - Impairment Testing, 3) Contract Costs - Interaction of Impairment Testing with Guidance in Other Topics, 4) Provisions for Losses on Construction-Type and Production-Type Contracts, 5) Scope of Topic 606, 6) Disclosure of Remaining Performance Obligations, 7) Disclosure of Prior-Period Performance Obligations, 8) Contract Modifications Example, 9) Contract Asset versus Receivable, 10) Refund Liability, 11) Advertising Costs, 12) Fixed-Odds Wagering Contracts in the Casino Industry and 13) Cost Capitalization for Advisors to Private Funds and Public Funds. The amendments affect the guidance in update 2014-09, which is effective for fiscal years beginning after December 15, 2017 for public business entities, including interim periods within those fiscal years.

For us, the amendments are effective January 1, 2018. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In December 2016, the FASB issued ASU 2016-19, Technical Corrections and Improvements. The update is to address suggestions received from stakeholders on the Accounting Standards Codification and to make other incremental improvements to GAAP. It contains amendments that affect a wide variety of Topics in the Accounting Standards Codification and applies to all reporting entities within the scope of the affected accounting guidance. Most of the amendments are effective upon issuance of the update. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): "Restricted Cash (a consensus of the FASB Emerging Issues Task Force)". The update addresses the diversity in the industry with respect to classification and presentation of changes in restricted cash on the statement of cash flows. These amendments require that a statement of cash flows explain the restricted cash change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. It affects those reporting entities that are required to evaluate whether they should consolidate a VIE. The amendments in this update are effective for fiscal years beginning after December 15, 2017 for public business entities, including interim periods within those fiscal years. For us, the amendments are effective January 1, 2018. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In October 2016, the FASB issued ASU 2016-17, Consolidation (Topic 810): "Interests Held through Related Parties That Are Under Common Control". The update was issued to amend the consolidation guidance on how a reporting entity that is a single decision maker of a variable interest entity ("VIE") should treat indirect interests in the entity held through related parties that are under common control with the reporting entity when determining whether it is the primary beneficiary of that VIE. It affects those reporting entities that are required to evaluate whether they should consolidate a VIE. The amendments in this update are effective for fiscal years beginning after December 15, 2017 for public business entities, including interim periods within those fiscal years. For us, the amendments are effective January 1, 2018. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In October 2016, the FASB issued ASU 2016-16, Income Taxes (Topic 740): "Intra-Entity Transfers of Assets Other Than Inventory". The update addresses income tax consequences of intra-entity transfers of assets other than inventory. It seeks to clarify the authoritative guidance about the prohibition of the recognition of current and deferred income taxes for intra-entity asset transfers until the asset has been sold to an outside party. Instead, this update now eliminates that prohibition and states that an entity should recognize the income tax consequences when the transfer occurs. The amendments in this update are effective for fiscal years beginning after December 15, 2017 for public business entities, including interim periods within those fiscal years. For us, the amendments are effective January 1, 2018. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): “Classification of Certain Cash Receipts and Cash Payments (a Consensus of the Emerging Issues Task Force)”. The update provides users with classification guidance on eight specific cash flow topics as follows: 1) Debt Prepayment or Debt Extinguishment Costs, 2) Settlement of Zero-Coupon Debt Instruments or Other Debt Instruments with Coupon Interest Rates That Are Insignificant in Relation to the Effective Interest Rate of the Borrowing, 3) Contingent Consideration Payments Made after a Business Combination, 4) Proceeds from the Settlement of Insurance Claims, 5) Proceeds from the Settlement of Corporate-Owned Life Insurance Policies, including Bank-Owned Life Insurance Policies, 6) Distributions Received from Equity Method Investees, 7) Beneficial Interests in Securitization Transactions and 8) Separately Identifiable Cash Flows and Application of the Predominance Principle. The amendments in this update are effective for fiscal years beginning after December 15, 2017 for public business entities, including interim periods within those fiscal years. For us, the amendments are effective January 1, 2018. We are currently evaluating the

impact of this ASU on our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): “Measurement of Credit Losses on Financial Instruments”. The update provides users with more useful information for decision making regarding expected credit losses on financial instruments/commitments to extend credit held by a reporting entity at each reporting date. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. Credit quality of the entity’s assets now plays a key role in this update. The amendments in this update are effective for fiscal years beginning after December 15, 2019 for public business entities, including interim periods within those fiscal years. For us, the amendments are effective January 1, 2020. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts with Customers (Topic 606): “Narrow-Scope Improvements and Practical Expedients”. The update addresses issues identified by the FASB-IASB Joint Transition Resource Group (TRG), a group formed in June, 2014 in order to inform the Boards about potential implementation issues that could arise as a result of organizations implementing the May, 2014 revenue guidance. It affects entities that enter into contracts with customers to transfer goods or services within an entity’s ordinary activities in exchange for consideration. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In May 2016, the FASB issued ASU 2016-11, Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): “Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting (SEC Update)”. The update is a result of adoption of Topic 606, Revenue from Contracts with Customers. SEC Staff Observer comments found in Topic 605 are therefore not recommended to be relied upon and have been superseded. The comments are found in the following topics: 1) Revenue and Expense Recognition for Freight Services in Process, 2) Accounting for Shipping and Handling Fees and Costs, 3) Accounting for Consideration Given by a Vendor to a Customer (including Reseller of the Vendor’s Products), and 4) Accounting for Gas-Balancing Arrangements. As these amendments require changes to the U.S. GAAP Financial Reporting Taxonomy, they will be incorporated into the proposed 2017 Taxonomy and finalized as part of the annual release process. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): “Improvements to Employee Share-Based Payment Accounting”. The update includes multiple provisions intended to simplify various aspects of the accounting for share-based payments, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments in this update are effective for public companies for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for any interim or annual period. We have evaluated the impact of this ASU on our consolidated financial statements and as a result, will adjust retained earnings in 2017 for the amounts previously recognized as windfall tax benefits in additional paid in capital.

In February 2016, the FASB issued Accounting Standards Update (“ASU”) 2016-02, Leases (Topic 842): “Recognition and Measurement of Financial Assets and Financial Liabilities”. The update supersedes Topic 840, Leases and requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. Topic 842 retains a distinction between finance leases and operating leases, with cash payments from operating leases classified within operating activities in the statement of cash flows. The amendments in this update are effective for fiscal years beginning after December 15, 2018 for public business entities, which for us means January 1, 2019. We are currently evaluating the impact of this ASU on our consolidated financial statements

In September 2015, the FASB issued ASU 2015-16, Business Combinations (Topic 805): “Simplifying the Accounting for Measurement-Period Adjustments”. The update eliminates the requirement to retrospectively adjust the provisional amounts recognized at the acquisition date with a corresponding adjustment to goodwill during the measurement period when new information is obtained about the facts and circumstances that existed as of the acquisition date, that if known, would have affected the measurement of the amounts initially recognized or would have resulted in the recognition of additional assets or liabilities. The amendments in this update are effective for fiscal years beginning after December 15, 2015, which for the Company means January 1, 2016, and should be applied prospectively to adjustments to provisional amounts that occur after the effective date of this update. Early application is permitted for financial statements that have not been issued. We have concluded that the adoption of this ASU will not have any significant impact on our consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): “Simplifying the Measurement of Inventory”. ASU 2015-11 requires inventory measured using any method other than last-in, first out (“LIFO”) or the retail inventory

method to be subsequently measured at the lower of cost or net realizable value, rather than at the lower of cost or market. Under this ASU, subsequent measurement of inventory using the LIFO and retail inventory method is unchanged. ASU 2015-11 is effective prospectively for fiscal years, and for interim periods within those years, beginning after December 15, 2016. Early application is permitted. We do not expect the adoption of this ASU will have any significant impact on its consolidated financial statements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2016, 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.

We had a revolving Credit and Security Agreement with General Electric Capital Corporation that called for interest to accrue based on a premium above either the current prime rate or current LIBOR rates. We terminated this credit facility in February 2016.

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, 2016, the fair value of our Notes was approximately $111.4 million compared to their face value of $143.75 million as of December 31, 2016. 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 $23.1 million change in the fair value of the derivative liability on our consolidated statements of operations in 2015.

At December 31, 2016, 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 AUDITING 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 Annual Report on 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, 2016. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework (2013).

Based on our assessment, management believes that, as of December 31, 2016, the Company's internal control over financial reporting is effective based on those criteria.

EisnerAmper 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, 2016, 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 Annual Report on Form 10-K.

Item 9B. OTHER INFORMATION

In the interest of maintaining consistency with the Company's 2016 Equity Incentive Plan, on March 13, 2017, the Company entered into (i) an amendment to the option agreements governing each option grant currently outstanding under the Company's 2009 Equity Incentive Plan, and (ii) an amendment to the restricted stock unit, or RSU, agreements governing each RSU grant currently outstanding under the 2009 Plan. The amendments provide for the automatic vesting upon a change of control of the Company of each option grant and RSU grant, as applicable, outstanding under the 2009 Plan. The forms of amendment are attached hereto as Exhibits 10.31 and 10.32, respectively, and are incorporated by reference herein.

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 2017 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 2017 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 2017 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 2017 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 2017 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 Teligent, Inc., dated October 23, 2015 (incorporated by reference to Exhibit 3.1 to the Company's Report on Form 8-K, filed October 23, 2015).

(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).

(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)# Form of Indemnification Agreement for Certain Directors (incorporated by reference to Exhibit 10.11 to the March 2009 8-K).

(10.9)#	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).
(10.10)#	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).
(10.11)+	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).
(10.12)	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).
(10.13)	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).
(10.14)+	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).
(10.15)	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).
(10.16)	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).
(10.17)	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).
(10.18)	Second Amendment to Credit Agreement, dated as of August 14, 2015, by and among Teligent, Inc., Igen, Inc. and Teligent Pharma, Inc. as Borrowers, General Electric Capital Corporation as Agent, and the Lenders signatory thereto (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 10-Q, filed November 9, 2015).
(10.19)	Third Amendment to Credit Agreement, dated as of September 16, 2015, by and among Teligent, Inc., Igen, Inc. and Teligent Pharma, Inc. as Borrowers, General Electric Capital Corporation as Agent, and the Lenders signatory thereto (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 10-Q, filed November 9, 2015).
(10.20)+	Asset Purchase Agreement, dated as of October 5, 2015, by between Concordia Pharmaceuticals Inc., S.à.r.l., Barbados Branch, on the one hand, and Teligent, Inc. and Teligent Jersey Limited, on the other hand

(incorporated by reference to Exhibit 10.3 to the Company's Report on Form 10-Q, filed November 9, 2015).

(10.21) Asset Purchase Agreement, dated October 12, 2015, between IGI Laboratories, Inc. and Alveda Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed October 13, 2015).

(10.22) Asset Purchase Agreement, dated October 12, 2015, between IGI Laboratories, Inc. and Alveda Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed October 13, 2015).

(10.23)	Contribution Agreement, by and between the Teligent, Inc. and Teligent Luxembourg S.à.r.l., dated as of November 13, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed November 16, 2015).
(10.24)	Loan Agreement, by and between Teligent, Inc. and Teligent Luxembourg S.à.r.l., dated as of November 13, 2015 (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed November 16, 2015).
(10.25)	Loan Agreement, by and between Teligent, Inc. and Teligent Canada Inc., dated as of November 13, 2015 (incorporated by reference to Exhibit 10.3 to the Company's Report on Form 8-K, filed November 16, 2015).
(10.26)	Distribution Agreement, by and between Teligent OÜ and Teligent Canada Inc., dated as of November 13, 2015 (incorporated by reference to Exhibit 10.4 to the Company's Report on Form 8-K, filed November 16, 2015).
(10.27)	First Amendment to Asset Purchase Agreement, by and between Teligent, Inc. and AstraZeneca Pharmaceuticals, LP, dated as of November 30, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed December 4, 2015).
(10.28)	First Amendment to Asset Purchase Agreement, dated December 10, 2015, by and between Concordia Pharmaceuticals Inc., S.à.r.l., Barbados Branch, on the one hand, and Teligent, Inc. and Teligent Jersey Limited, on the other hand (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed December 15, 2015).
(10.29)	Trademark Assignment Agreement, dated December 10, 2015, by and between Concordia Pharmaceuticals Inc., S.à.r.l., Barbados Branch, on the one hand, and Teligent Jersey Limited, on the other hand (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed December 15, 2015).
(10.30)#	Teligent, Inc. 2016 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed May 27, 2016).
(10.31)#*	Form of Amendment to Outstanding Option Agreements under the Company's 2009 Equity Incentive Plan.
(10.32)#*	Form of Amendment to Outstanding RSU Agreements under the Company's 2009 Equity Incentive Plan.
(21)	List of Subsidiaries (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 10-K, filed March 15, 2016).
(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.

(101)*	The following financial information from this Annual Report on Form 10-K for the year ended December 31, 2016, formatted in XBRL (Extensible Business Reporting Language) and furnished electronically herewith: (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.

Teligent, Inc.

By: /s/ Jason Grenfell-Gardner
Jason Grenfell-Gardner
President and Chief Executive Officer

Date: March 15, 2017

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 15, 2017
/s/ Jenniffer Collins Jenniffer Collins	Chief Financial Officer (Principal Financial Officer)	March 15, 2017
/s/ Steven Koehler Steven Koehler	Director	March 15, 2017
/s/ James Gale James Gale	Director	March 15, 2017
/s/ Narendra Borkar Narendra Borkar	Director	March 15, 2017
/s/ Bhaskar Chaudhuri Bhaskar Chaudhuri	Director	March 15, 2017
/s/ John Celentano John Celentano	Director	March 15, 2017
/s/ Carole Ben-Maimon Carole Ben-Maimon	Director	March 15, 2017

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Teligent, Inc. and subsidiaries (formerly known as IGI Laboratories, Inc.)

We have audited the accompanying consolidated balance sheets of Teligent, Inc. and subsidiaries (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2016. In connection with our audits of the consolidated financial statements, we have also audited financial statement schedule "Schedule II - Valuation and Qualifying Accounts" for each of the years in the three-year period ended December 31, 2016. The financial statements and financial statement schedule are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule 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 Teligent, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information stated therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Teligent, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2016, based on criteria established in the 2013 Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated March 15, 2017 expressed an unqualified opinion thereon.

/s/ EISNERAMPER LLP

Iselin, New Jersey
March 15, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Teligent, Inc. and subsidiaries (formerly known as IGI Laboratories, Inc.)

We have audited Teligent, Inc. and Subsidiaries' (the "Company") internal control over financial reporting as of December 31, 2016, based on criteria established in the 2013 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.

An entity'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. An entity'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 entity; (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 entity are being made only in accordance with authorizations of management and directors of the entity; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the entity'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, Teligent, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in the 2013 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 Teligent, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2016, and our report dated, March 15, 2017, expressed an unqualified opinion thereon.

/s/ EISNERAMPER LLP

Iselin, New Jersey
March 15, 2017

F-3

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

	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$66,006	$87,191
Accounts receivable, net	21,735	14,028
Inventories	12,708	8,985
Prepaid expenses and other receivables	2,847	6,597
Total current assets	103,296	116,801
Property, plant and equipment, net	26,215	8,706
Intangible assets, net	52,465	54,320
Goodwill	446	426
Other	804	482
Total assets	$183,226	$180,735
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$4,614	$3,955
Accrued expenses	10,349	6,267
Deferred income, current	—	476
Capital lease obligation, current	—	70
Total current liabilities	14,963	10,768
Convertible 3.75% senior notes, net of debt discount and debt issuance costs (face of $143,750)	111,391	102,964
Deferred tax liability	205	244
Total liabilities	126,559	113,976
Stockholders' equity:		
Series A Convertible Preferred stock, $0.01 par value, 100 shares authorized; 0 shares issued and outstanding as of December 31, 2016 and 2015, respectively	—	—
Series C Convertible Preferred stock, $0.01 par value, 1,550 shares authorized; 0 shares issued and outstanding as of December 31, 2016 and 2015, respectively	—	—
Common stock, $0.01 par value, 100,000,000 shares authorized; 53,148,441 and 53,000,689 shares issued and outstanding as of December 31, 2016 and December 31, 2015, respectively	551	549
Additional paid-in capital	102,624	99,258
Accumulated deficit	(44,903)	(32,918)
Accumulated other comprehensive loss, net of taxes	(1,605)	(130)
Total stockholders' equity	56,667	66,759
Total liabilities and stockholders' equity	$183,226	$180,735

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

F-4

TELIGENT, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
For the years ended December 31, 2016, 2015 and 2014
(in thousands, except shares and per share information)

	2016	2015	2014
Revenues:			
Product sales, net	$ 65,904	$ 43,497	$ 32,104
Research and development services and other income	977	753	1,636
Total revenues	66,881	44,250	33,740
Costs and Expenses:			
Cost of revenues	32,194	22,935	16,948
Selling, general and administrative expenses	15,005	11,336	5,976
Product development and research expenses	17,140	13,171	6,910
Total costs and expenses	64,339	47,442	29,834
Operating income (loss)	2,542	(3,192)	3,906
Other Income (Expense):			
Change in the fair value of derivative liability	—	23,144	2,300
Foreign currency exchange gain (loss)	(936)	109	—
Interest and other expense, net	(13,304)	(13,358)	(782)
Income (loss) before income tax expense (benefit)	(11,698)	6,703	5,424
Income tax expense	287	35	173
Net income (loss) income attributable to common stockholders	$ (11,985)	$ 6,668	$ 5,251
Basic earnings (loss) per share	$ (0.23)	$ 0.13	$ 0.11
Diluted earnings (loss) per share	$ (0.23)	$ (0.07)	$ 0.09
Weighted average shares of common stock outstanding:			
Basic	53,078,158	52,872,814	49,817,721
Diluted	53,078,158	67,111,995	64,207,190

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

TELIGENT, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
For the years ended December 31, 2016, 2015 and 2014
(in thousands)

	2016	2015	2014
Net income (loss)	$(11,985)	$6,668	$5,251
Other comprehensive loss, net of tax			
Foreign currency translation adjustment			