

Edgar Filing: Teligent, Inc. - Form 10-K

Teligent, Inc.
Form 10-K
March 19, 2018

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2017

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

of incorporation or organization)

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

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

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

..

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold, as of the last business day of the registrant's most recently completed second fiscal quarter was \$394.8 million.

As of March 6, 2018, the registrant had 53,496,889 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 21, 2018.

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 25 generic topical pharmaceutical products and four branded generic pharmaceutical products. In Canada, we sell over 30 generic and branded generic injectable products and medical devices. Generic pharmaceutical products are bioequivalent to their brand name counterparts. We also provide contract manufacturing services to the pharmaceutical, over-the-counter, ("OTC"), and cosmetic markets. We operate our business under one segment.

Our common stock is 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.

In 2014, we acquired 23 drug products that had been previously approved by the United States Food and Drug Administration, or FDA. Our pipeline includes 31 Abbreviated New Drug Applications, or ANDAs, on file with the FDA, for additional pharmaceutical products. In addition, we have four submissions on file with Health Canada. We have an additional 45 product candidates at various stages of our development pipeline. We submitted four ANDAs in 2017. 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 2017. We intend to continue to submit further ANDAs to the FDA and ANDSs to Health Canada in 2018. 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 eight 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,

2

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 over 30 products. Teligent continues to transition these products to distribute them under a Teligent Canada label.

Teligent OÜ. Teligent OÜ currently has 13 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 addition to certain products and active pharmaceutical ingredients ("API's") for Teligent Pharma, Inc. in the U.S. We built and developed a laboratory to support analytical chemistry, quality control, and formulation development to support our Teligent US and Teligent Canada supply chain management and technical services teams.

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. This building renovation also houses our regulatory affairs, supply chain and corporate service teams.

We continue with the significant expansion and utilities upgrade of our manufacturing facility at 105 Lincoln Avenue in Buena, New Jersey. In December 2017, we received the Temporary Certificate of Occupancy (TCO) to begin using the first phase of completed work in our manufacturing facility, which includes a state-of-the-art quality control and microbiology lab for the testing of our pharmaceutical products. The expanded facility will increase our manufacturing capability 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 between four and eight 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 \$60 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.

Based on IQVIA data, the addressable market, as of January 2018, for the 32 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. Additionally, we plan to file further ANDSs with Health Canada in 2018. We also have 45 additional product candidates in various stages of development.

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.

On November 13, 2015, we formed Teligent Canada, and completed the acquisition of Alveda. Teligent Canada currently has eight 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.

Our Contract Manufacturing and Development Business

We 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.

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

We develop and market a diversified product portfolio focused on alternative dosage forms. 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 contract manufacturing services to the pharmaceutical, OTC, and cosmetic markets. 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 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

4

Our TICO strategy originated from our opportunity to leverage our value chain, which we have developed and strengthened through our topical portfolio. Our 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 expansion of our existing manufacturing facility, 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 25 topical products under our own label. We have received FDA approvals for 20 topical generic products from our internally developed pipeline in 2017. In our topical pipeline, we have 29 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, eight of which were approved. We are targeting to develop and file further regulatory submissions with the FDA in 2018. 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.

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 29 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 the NDA for one of those three optioned injectable products from Valeant. In March 2015, we completed the purchase of the final two NDAs for the optioned injectable products 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.

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 a portfolio of sterile injectable products we acquired in 2014, which 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 pursue 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 filed one ANDA in the fourth quarter of 2017 for a generic version of an oral orphan drug. 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. We are currently working with a contract research organization to develop three generic ophthalmic products.

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 over 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, 2017, and 2016, 57% and 41% 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, 2017, Cardinal accounted for 47% of our accounts receivable, ABC accounted for 15% of our accounts receivable, and McKesson accounted for 14% of our accounts receivable. 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.

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. There are generally three major negotiating entities in the US market. Walgreens Boots Alliance Development (WBAD) consists of Walgreens, AmerisourceBergen's PRxO Generics program, and Econdisc members. Red Oak Sourcing consists of CVS and Cardinal's source program. Finally, ClarusOne consists of Walmart, RiteAid and McKesson's OneStop program. A loss of any of these major entities could result in a significant reduction in revenue.

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, 2017, approximately 86% of our contract services revenue was derived from pharmaceutical customers, as compared to 90% of total contract services revenue for the year ended December 31, 2016. None of our contract manufacturing services customers represented 10% of total revenue for the year ended December 31, 2017, and one of our contract manufacturing services customers represented 10% of total revenue for the year ended December 31, 2016.

Concentration of Risk. In 2017, we had sales to three customers which individually accounted for more than 10% of our total revenue. These customers had sales of \$18.7 million, \$9.9 million and \$9.6 million, respectively, and represented 57% of total revenues in the aggregate. Accounts receivable related to these major customers comprised of 13%, 14% and 43%, respectively, and represented 70% of all accounts receivable as of December 31, 2017. 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 of 20%, 56% and 5%, respectively, and represented 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 of 43%, 33% and 6%, respectively, and represented 83% of all accounts receivable as of December 31, 2015.

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, 2017, domestic net revenues were \$53.5 million and foreign net revenues were \$13.8 million. As of December 31, 2017, domestic net assets were \$117.7 million and foreign assets were \$72.3 million. 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 assets were \$120.0 million and foreign assets were \$63.2 million. For the year ended December 31, 2015, domestic net revenues were \$42.7 million and foreign net revenues were \$1.6 million. As of December 31, 2015, domestic assets were \$129.0 million and foreign assets were \$51.7 million.

Our Products

We recorded net revenue from one product, Econazole Nitrate Cream 1%, which accounted for 4%, 8% and 45% of total revenues in 2017, 2016 and 2015, respectively. Lidocaine Ointment 5%, which we launched at the end of the first quarter of 2016, accounted for 17%, 23% and 0% of total revenues in 2017, 2016, and 2015, respectively. Zantac for injection, which the Company acquired in the fourth quarter of 2015, accounted for 10%, 3% and 0% of total revenues in 2017, 2016 and 2015.

Teligent United States Topical Pharmaceutical Products

Product	Formulation	Presentations	Brand equivalent	Therapeutic Classification
Betamethasone Dipropionate (Augmented), 0.05%	Ointment	15g, 50g	DIPROLENE®	Topical Corticosteroid
Betamethasone Dipropionate (Augmented), 0.05%	Lotion	30mL, 60mL	DIPROLENE®	Topical Corticosteroid
Clindamycin Phosphate 1%	Topical Solution	30mL, 60mL	Cleocin®	Topical Anti-infective
Clobetasol 0.05%	Lotion	2oz, 4oz	Clobetasol	Topical Corticosteroid
Clobetasol Propionate 0.05%	Gel	15g, 30g, 60g	Embeline®	Topical Corticosteroid
Clobetasol Propionate Emollient 0.05%	Cream	15g, 30g, 45g, 60g	TemovateE®	Topical Corticosteroid
Desoximetasone 0.25%	Ointment	15g, 60g, 100g	Topicort®	Topical Corticosteroid
Diclofenac Sodium 1.5%	Topical Solution	150mL	Pennsaid®	Topical Anti-inflammatory
Econazole Nitrate 1%	Cream	15g, 30g, 85g	Spectazole®	Topical Anti-fungal
Erythromycin 2%	Gel	30g, 60g	Erygel®	Topical Corticosteroid
Erythromycin 2%	Topical Solution	60 mL	Erythromycin Topical Solution 2%	Topical Corticosteroid
Fluocinolone Acetonide 0.01%	Topical Solution	60mL	Synalar®	Topical Corticosteroid
Fluocinolone Acetonide 0.01%	Cream	15g, 60g	Synalar®	Topical Corticosteroid
Fluocinolone Acetonide 0.025%	Ointment	15g, 60g	Synalar®	Topical Corticosteroid
Fluocinolone Acetonide 0.025%	Cream	15g, 60g	Synalar®	Topical Corticosteroid
Flurandrenolide 0.05%	Ointment	15g, 30g, 60g	Cordran®	Topical Corticosteroid
Hydrocortisone Butyrate 0.1%	Lotion	118mL, 59 mL	Locoid®	Topical Corticosteroid
Lidocaine 4%	Topical Solution	50mL	Xylocaine®	Topical Anesthetic
Lidocaine 5%	Ointment	35.44g	Xylocaine®	Topical Anesthetic
Nystatin/Triam 100,000 Nystatin units/1mg per gram	Ointment	15g, 30g, 60g	Mykacet®	Topical Anti-fungal
Triamcinolone Acetonide 0.025%	Lotion	60ml	Triamcinolone Acetonide	Topical Corticosteroid
Triamcinolone Acetonide 0.1%	Ointment	15g, 80g, 11b jar	Kenalog®	Topical Corticosteroid
Triamcinolone Acetonide 0.1%	Lotion	60mL	Triamcinolone Acetonide	Topical Corticosteroid
Triamcinolone Acetonide 0.1%	Cream	15g, 30g, 80g	Kenalog®	Topical Corticosteroid
Triamcinolone Acetonide 0.5%	Ointment	15g	Kenalog®	Topical Corticosteroid

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) ®	25mg/ml	Injectable	2ml, 6ml, 40ml Vials	NDA	Drugs for peptic ulcer and gastro-oesophageal related disorders (GORD)
Zinacef (Cefuroxime) ™	750mg, 1.5g, 7.5g	Injectable	Vial, Twist Vial	NDA	Antibacterial for systemic use

Teligent Canada Products (1)

Product	Strength	Formulation	Presentations	Brand equivalent	Dossier type held by Teligent	Therapeutic Classification
Acetylcysteine	200 mg/ml	Injectable	10ml and 30 ml vials	Mucomyst® Parvovex®	ANDS	Antidote
Atropine	0.4 mg/ml, 0.6 mg/ml	Injectable	1 ml vials	N/A	DINA	Antimuscarinic, antispasmodic
Baclofen	0.05 mg/ml, 0.5mg/ml, 2mg/ml	Injectable	1mL, 5mL, 20mL ampoules	Lioresal®	ANDS	Muscle Relaxant
Ibuprofen for Intravenous Infusion	100 mg/ml	Injectable	8 ml vial	Caldolor®	NDS	Nonsteroidal Antiinflammatory Agent
Cyanocobalamin (2)	1000 mcg/ml	Injectable	1 mL ampoule, 10 ml vial	N/A	DINA	Hematopoietic
Diazepam	5 mg/mL	Injectable	2mL ampoules	Valium®	ANDS	Benzodiazepine
Dimenhydrinate	50 mg, 250 mg	Injectable	1 ml ampoule, 5 ml vial	Gravol®	DINA	Antihistamine
Dobutamine (2)	12.5 mg/ml	Injectable	20 mL vial	N/A	ANDS	Sympathomimetic
Epinephrine	1 mg/ml	Injectable	1 ml ampoule	Adrenalin®	DINA	Cardiac Stimulant
Ergonovine Maleate	0.25 mg/ml	Injectable	1 ml ampoule	N/A	DINA	Oxytocic
Fentanyl	50 mcg/mL	Injectable	2mL ampoule	Sublimaze®	ANDS	Opiate Anesthetic
Furosemide	10 mg/ml	Injectable	2 ml ampoule	Lasix®	ANDS	Diuretic
Gemcitabine	10 mg, 200 mg, 1 g	Injectable	10 mg, 200 mg, 1 g vials	Gemzar®	ANDS	Antineoplastic agent
Gentamicin (2)	10 mg/ml, 40 mg/ml	Injectable	2mL ampoule	Garamycin®	ANDS	Antibiotic
Irinotecan Hydrochloride	20 mg/ml	Injectable	2 ml, 5 ml, 25 ml vials	Camptosar®	ANDS	Antineoplastic agent
Lidocaine 1%	10 mg/mL	Injectable	5 ml and 10 ml polyampoule	Xylocaine®	DINA	Local Anesthetic
Lidocaine 1%	10 mg/ml	Injectable	20 ml and 50 ml vials	Xylocaine®	DINA	Local Anesthetic
Lidocaine 2%	20 mg/ml	Injectable	5 ml and 10 ml polyampoule	Xylocaine®	DINA	Local Anesthetic
Lidocaine 2%	20 mg/ml	Injectable	20 ml and 50 ml vials	Xylocaine®	DINA	Local Anesthetic
Lidocaine 2% with epinephrine	20 mg/ml & 0.01 mg/mL	Injectable	20 ml and 50 ml vials	Xylocaine®	DINA	Local Anesthetic
Lidocaine Hydrochloride Topical Solution USP 4%	40 mg/ml	Topical Solution	50mL	Xylocaine®	DINA	Topical Anesthetic
Lidocaine Ointment USP 5%	50 mg/g	Ointment	35g	Xylocaine®	DINA	Topical Anesthetic
Methylene Blue	10 mg/mL	Injectable	5mL ampoule	N/A	DINA	Antidote
Naloxone	0.4mg / ml	Injectable	1mL ampoule	Narcan	ANDS	Opiate Antagonist
Piperacillin and Tazobactam	2g, 0.25 g, 3 g, 0.375 g, 4 g,	Injectable	2.25 g, 3.375 g, 4.5 g vials	Tazocin®	ANDS	Antibacterial for systemic use

Edgar Filing: Teligent, Inc. - Form 10-K

Sodium Chloride	0.5 g	Injectable	10 ml vials	N/A	DINA	Diluent
Sterile Water for Injection	0.9%	Injectable	10 ml polyampoule	N/A	DINA	Diluent
Succinylcholine Chloride	100%	Injectable	10 ml and 20 ml vials	Quelicin®	DINA	Muscle Relaxant
	20 mg/mL					

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

(2) Product approved in 2017

Edgar Filing: Teligent, Inc. - Form 10-K

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	Cefotetan ®	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 HCl ®	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	ANDA	Muscle Relaxant
Edrophonium	10 mg/mL	Injectable	1 mL ampule and 10 mL vial	Enlon®	NDA	Acetylcholinesterase inhibitor
MVI-12	N/A	Injectable		N/A	NDA	

Edgar Filing: Teligent, Inc. - Form 10-K

Naloxone HCl	0.4 mg/mL, 1 mg/mL	Injectable	10 mL ampules and 5 mL vials 1 mL 5 mL and 10 mL vials	N/A	ANDA	Systemic multivitamin Opitate Antagonist
Naloxone HCl (preservative free)	0.4 mg/mL	Injectable	1 mL vials	N/A	ANDA	Opitate Antagonist
Tobramycin Sulfate	10 mg/mL, 40 mg/mL	Injectable	2 mL and 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 2017, 2016 or 2015.

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 38 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 ("CRO"). Our injectable development is primarily conducted in house with some assistance from certain CRO's.

We have been steadily increasing our investment in R&D as we believe that R&D is the future of the Company. We incurred \$19.3, \$17.1, and \$13.2 million in R&D expenses in 2017, 2016 and 2015, respectively. 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 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 a period 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 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. We currently do not have any applications in development that would utilize this track.

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: Perrigo Company, Sandoz (the generic pharmaceutical division of Novartis AG), Taro Pharmaceutical Industries, Ltd., Mylan N.V., and Teva Pharmaceutical Industries, Ltd. Collectively, these five competitors control approximately 59% of the generic topical market by value based on IQVIA data from December 2017. 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 three dominant companies in the injectable generic drug market in the United States consist of Fresenius Kabi USA, Hospira, Inc. (a subsidiary of Pfizer, Inc.) and Sandoz (the generic pharmaceutical division of Novartis AG). Collectively, these three competitors control approximately 55% of the generic injectable market by value based on IQVIA data from December 2017. 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. 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 12 to the Company's Consolidated Financial Statements included elsewhere in this Annual Report.

Intellectual Property

15

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. In 2017 we acquired an additional 3.0 acres of adjacent land in support of our facility expansion. We now own a total of 11.44 acres at our Buena facility. 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 100,000 square feet. The expanded facility will increase our manufacturing capability 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. Our capabilities encompass a full suite of competencies, including manufacturing, regulatory, quality assurance and in-house validation.

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 9,500 square feet of corporate office space in Iselin, New Jersey, approximately 4,000 square feet of office space in Toronto, Canada and approximately 3,000 square feet of office and laboratory space in Tallinn, Estonia.

Employees

On December 31, 2017, we had a total of 183 full-time employees, including eight full-time employees in Canada and 13 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 third-parties 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 1B. UNRESOLVED STAFF COMMENTS

None.

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

16

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, 2017, our stockholders' equity was \$44.8 million and we had an accumulated deficit of \$60.1 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 57% of our revenue for the year ended December 31, 2017, and three of our customers accounted for 43% of our revenue for the year ended December 31, 2016. 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 17% and 23% of our revenue for the years ended December 31, 2017 and 2016, 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 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 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. 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, 2017, and remaining costs accrued at December 31, 2017 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 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 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 and if contractually obligated, we issue 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

Edgar Filing: Teligent, Inc. - Form 10-K

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;

the Foreign Corrupt Practices Act (FCPA) including its anti-bribery provisions, which make it unlawful for certain classes of persons and entities to make payments to foreign government officials to assist in obtaining or retaining business; 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, including in-process research and development. As of December 31, 2017 the value of our goodwill and intangible assets net of accumulated amortization was \$56.0 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-marketing 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 or retain 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.

We have identified material weaknesses in our internal control over financial reporting, and 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. We have identified material weaknesses in our internal control over financial reporting, and if additional material weaknesses are found in our internal controls in the future, if we fail to remediate our existing material weaknesses, 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.

We have identified material weaknesses in our internal control over financial reporting, which could continue to impact negatively our ability to report our results of operations and financial condition accurately and in a timely manner.

As required by Section 404 of the Sarbanes-Oxley Act of 2002, management has conducted an evaluation of the effectiveness of our internal control over financial reporting at December 31, 2017. We identified a number of material weaknesses in our internal

control over financial reporting and concluded that, as of December 31, 2017, we did not maintain effective control over financial reporting based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. For a detailed description of these material weaknesses, see Item 9A, "Controls and Procedures." Each of our material weaknesses results in more than a remote likelihood that a material misstatement of the annual or interim financial statements that we prepare will not be prevented or detected. As a result, we must perform extensive additional work to obtain reasonable assurance regarding the reliability of our financial statements. As described in Item 9A, "Controls and Procedures" we restated our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. Moreover, other material weaknesses may be identified.

We are in the process of remedying all of the identified material weaknesses, and this work will continue during fiscal 2018 and beyond. For a detailed description of our remedial efforts, see Item 9A, "Controls and Procedures." There can be no assurance as to when all of the material weaknesses will be remedied. Until our remedial efforts are completed, management will continue to devote significant time and attention to these efforts, and we will continue to incur expenses associated with the additional procedures and resources required to prepare our Consolidated Financial Statements. Certain of our remedial actions, such as hiring additional qualified personnel to implement our reconciliation and review procedures, will be ongoing and will result in our incurring additional costs even after our material weaknesses are remedied.

If we are unsuccessful in implementing or following our remediation plan, or fail to update our internal control over financial reporting as our business evolves or to integrate acquired businesses into our controls system, we may not be able to timely or accurately report our financial condition, results of operations or cash flows or to maintain effective disclosure controls and procedures. If we are unable to report financial information in a timely and accurate manner or to maintain effective disclosure controls and procedures, we could be subject to, among other things, regulatory or enforcement actions by the SEC, an inability for us to be accepted for listing on any national securities exchange in the near future, securities litigation and a general loss of investor confidence, any one of which could adversely affect our business prospects and the market value of our Common Stock. Further, there are inherent limitations to the effectiveness of any system of controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. We could face additional litigation exposure and a greater likelihood of an SEC enforcement or other regulatory action if further restatements were to occur or other accounting-related problems emerge. In addition, any future restatements or other accounting-related problems may adversely affect our financial condition, results of operations and cash flows.

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, 2017, we had federal net operating loss carry forwards, or NOLs, of approximately \$41.7 million which expire from 2020 through 2037. 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 \$23.1million) 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 subject to the provisions of ASC 740-10-25, Income Taxes (ASC 740). ASC 740 prescribes a more likely-than-not threshold for the financial statement recognition of uncertain tax positions. ASC 740 clarifies the accounting for income taxes by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. On a quarterly basis, we undergo a process to evaluate whether income tax accruals are in accordance with ASC 740 guidance on uncertain tax positions. For federal purposes, (except for the years 2014 and 2015, which have been examined by the Internal Revenue Services), post 1998 tax years remain open to examination as a result of net operating loss carryforwards. We are currently open to audit by the appropriate state income taxing authorities for tax years 2013 through 2016.

The recently passed comprehensive federal tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the “Tax Cuts and Jobs Act,” or TCJA, which significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a “worldwide” system of taxation to a territorial system. Our net deferred tax assets and liabilities have been revalued at the newly enacted U.S. corporate rate, and the impact was recognized in our tax expense in the year of enactment. We continue to examine the impact this tax reform legislation may have on our business. The overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected.

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, 2017, the average daily trading volume of our common stock on the NASDAQ Global Select Market was approximately 430,788 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, 2017, and our management concluded that our disclosure controls and procedures were not effective as of December 31, 2017, solely because of the material weakness in our internal control over financial reporting described herein in Item 9A(ii).

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.

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. If such stockholders sold a significant amount of stock it could have an adverse effect on the price of the 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 \$2.82 in the fourth quarter of 2017 and a high of \$9.54 in the second quarter of 2017. 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 in the markets in which we compete, and other external factors;

33

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.

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, 2017, our total consolidated indebtedness was \$143.75 million. The Notes are due in December 2019. 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.

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.

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 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. In 2017 we acquired an additional 3.0 acres of adjacent land in support of our facility expansion. We now own a total of 11.44 acres at our

Buena facility. 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 9,500 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 3,000 square feet of office and laboratory space in Tallinn, Estonia.

Item 3. LEGAL PROCEEDINGS

On March 2, 2001, we became aware of environmental contamination resulting from an unknown heating oil leak at our former manufacturing facility. We 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 \$118,000 remains accrued as of December 31, 2017. Based on information provided to us from our environmental consultant and what is known to date, we believe the reserve is sufficient for the remaining remediation of the environmental contamination. There is a possibility, however, that the remediation costs may exceed our estimates.

The restricted cash, included in other assets on the Consolidated Balance Sheet of \$120,000 as of December 31, 2017 and \$122,000 as of December 31, 2016, 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 us 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 is collectively referred 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 is collectively referred to as Horizon, filed a complaint in the United States District Court for the District of New Jersey against us 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 us 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, we filed answers, affirmative defenses and counterclaims with respect to the complaints filed by Horizon. In those filings, we 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, we filed along with Horizon a stipulation of dismissal to dismiss the cases. The court entered an order dismissing the cases on May 2, 2016. On May 9, 2016, we along with Horizon entered into a settlement agreement. Under the settlement agreement, we 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, we cannot estimate if or when any of those earlier events might occur. No consideration was exchanged as part of the settlement. We have not recorded accruals related to this case and have not yet received final approval.

On December 4, 2015, Galderma Laboratories, L.P. and Galderma S.A., which is collectively referred 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, we entered into a Settlement and License Agreement with Galderma, the terms of which are confidential. On January

22, 2016, the case was dismissed with prejudice.

To date, twelve putative class action antitrust lawsuits were filed against us, along with co-defendants including Taro Pharmaceuticals U.S.A., Inc. and Perrigo New York Inc. One “opt-out” action has additionally been filed against us along with thirty-five generic manufacturer co-defendants regarding the pricing of econazole nitrate cream and twenty-nine additional drug products not manufactured or sold by us. All actions have been transferred by the Judicial Panel on Multidistrict Litigation to the Eastern District of Pennsylvania for pre-trial proceedings as part of the In re Generic Pharmaceuticals Pricing Antitrust Litigation matter, and the class actions have been consolidated into direct purchaser, end payer and indirect reseller actions.

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 until the time the defendants’ allegedly unlawful conduct ceased or will cease.

The class plaintiffs allege a conspiracy by thirty-six generic manufacturers, including us, to fix prices for thirty drug products including econazole nitrate cream, in violation of federal antitrust laws or state antitrust, consumer protection, and other laws. The

opt-out plaintiffs seek treble damages for alleged price overcharges for the thirty drug products identified in the complaint during the alleged period of conspiracy, and also seek injunctive relief against the defendants.

All of these cases are in their initial stages and motions to dismiss have been filed with respect to each of the complaints. 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 believe these cases are without merit, and we intend to vigorously defend against these claims.

On October 20, 2017, a Demand for Arbitration was filed with the American Arbitration Association by Stayma Consulting Services, Inc. (“Stayma”) against the Company regarding the Company’s development and manufacture for Stayma of two generic drug products, one a lotion and one a cream, containing 0.05% of the active pharmaceutical ingredient flurandrenolide. The Company developed the two products and Stayma purchased commercial quantities of each; however, Stayma now alleges that the Company breached agreements between the parties by developing an additional and different generic drug product, an ointment, containing flurandrenolide, and failing to meet certain contractual requirements. Stayma seeks monetary damages. Due to the early stage of this matter, 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 believe this case is without merit, and we intend to vigorously defend against these claims. We filed a counter-claim against Stayma for its failure to pay several past due invoices of approximately \$1.7 million relating to the development and commercial supply of the two subject products.

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 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
2017		
First Quarter	8.30	6.46
Second Quarter	9.54	7.60
Third Quarter	9.27	5.97
Fourth Quarter	7.34	2.82

Stockholders

As of March 6, 2018, there were approximately 359 stockholders of record of our 53,496,889 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.

39

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 audited consolidated financial statements of the Company, certain of which 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,				
	2017	2016	2015	2014	2013
(In thousands, except per share data)					
Revenues	\$67,251	\$66,881	\$44,250	\$33,740	\$18,224
Gross profit	27,372	34,687	21,315	16,972	6,145
Operating income (loss)	(11,797)	2,542	(3,192)	3,906	(82)
Interest and other non-operating income (expense)	(3,479)	(14,240)	9,895	1,518	(199)
Foreign currency exchange gain (loss)	7,719	(936)	109	—	—
Pretax income (loss)	(15,276)	(11,698)	6,703	5,424	(281)
Income tax provision (benefit)	(85)	287	35	173	(197)
Net income (loss)	\$(15,191)	\$(11,985)	\$6,668	\$5,251	\$(84)
Preferred stock dividend	—	—	—	—	(1,308)
Net income (loss) attributable to common stockholders	\$(15,191)	\$(11,985)	\$6,668	\$5,251	(1,392)
Weighted average shares outstanding:					
Basic	53,324	53,078	52,873	49,818	43,518
Diluted	53,324	53,078	67,112	64,207	43,518
PER SHARE:					
Net income (loss):					
Basic	(0.28)	(0.23)	0.13	0.11	(0.03)
Diluted	(0.28)	(0.23)	(0.07)	0.09	(0.03)
BALANCE SHEET DATA:					
Current assets	\$64,532	\$103,296	\$116,801	\$177,218	\$10,558
Net property, plant & equipment	68,355	26,215	8,706	3,262	2,623
Total assets	189,986	183,226	184,762	197,078	15,427
Current liabilities	24,097	14,963	10,768	13,002	5,221
Long-term obligations, less current installments	121,136	111,596	107,235	144,942	3,015
Shareholders’ equity	44,753	56,667	66,759	39,134	7,191
CASH FLOW DATA:					
Cash provided by (used in) operating activities	\$400	\$(798)	\$(15,513)	\$(3,891)	\$(618)
Cash used in investing activities	(40,429)	(20,076)	(53,068)	(3,792)	(2,113)
Cash provided by (used in) financing activities	269	(10)	(3,111)	164,465	2,296
Increase/(Decrease) in cash and cash equivalents	(39,760)	(20,884)	(71,692)	156,782	(435)

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. and its subsidiaries (collectively the "Company") is a specialty generic pharmaceutical company. Our mission is to become a leader in the specialty generic pharmaceutical market. Under our own label, we currently market and sell generic topical and generic and branded generic injectable pharmaceutical products in the United States and Canada. In the United States we currently market 25 generic topical pharmaceutical products and four branded generic pharmaceutical products. In Canada we sell a total of over 30 generic and branded generic injectable products and medical devices. Generic pharmaceutical products are bioequivalent to their brand name counterparts. We also provide contract manufacturing services to the pharmaceutical, over-the-counter, ("OTC"), and cosmetic markets. We operate our business under one segment. Our common stock is 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, 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.

In 2014, we acquired 23 drug products that had been previously approved by the United States Food and Drug Administration, or FDA. Our pipeline includes 31 Abbreviated New Drug Applications, or ANDAs filed with the FDA, for additional pharmaceutical products. In addition, we have five submission filings on file with Health Canada. We have an additional 45 product candidates at various stages of our development pipeline. We submitted four ANDAs in 2017. 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 2017. We intend to continue to submit further ANDAs to the FDA and ANDSs to Health Canada in 2018. We will also seek to license or acquire further products, intellectual property, or pending applications to expand our portfolio.

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 ended December 31, 2017 compared to fiscal year ended December 31, 2016

We had a net loss of \$15.2 million, or \$0.28 per share, in 2017 compared to net loss of \$12.0 million, or \$0.23 per share, in 2016.

Revenues (in thousands):

Components of Revenue:	Year Ended		Increase/(Decrease)	
	December 31,		\$	%
	2017	2016		
Product sales, net	\$66,999	\$65,904	\$ 1,095	2 %
Research and development services and other income	252	977	(725)	(74)%
Total Revenues	\$67,251	\$66,881	\$ 370	1 %

The increase in product sales for the year ended December 31, 2017 as compared to the same period in 2016 was primarily due to increased revenue from the expansion of our own generic pharmaceutical product line, increased revenue from Lidocaine Hydrochloride topical solution and Zantac injectable and increased revenue from our specialty generic injectable portfolio in Canada. These increases were offset by a decrease in contract manufacturing revenues of \$8.0 million from the same period in the prior year, specifically related to a decline in sales to one of our customers. Consistent with our strategy, we continue to expect contract manufacturing revenue as a percentage of total revenue to decline over time.

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		Increase/(Decrease)	
	December 31,		\$	%
	2017	2016		
Cost of revenues	\$39,879	\$32,194	\$ 7,685	24 %
Selling, general and administrative	19,904	15,005	4,899	33 %
Product development and research	19,265	17,140	2,125	12 %
Totals costs and expenditures	\$79,048	\$64,339	\$ 14,709	23 %

Cost of revenues increased for the year ended December 31, 2017 as compared to the same period in 2016 as a result of the increase in total revenue. Cost of revenues increased as a percentage of total revenue to 59% for the year ended December 31, 2017 as compared to 48% for the same period in 2016. The increase in cost of revenue as a percentage of sales was primarily due to the increased revenue from our own generic pharmaceutical product line. Increase in cost of sales as a percentage of revenue was driven by new product launches as well as changes in product mix, pricing and related fees, such as wholesale fees, in addition to customer and product mix for our contract services revenue. For the

year ended December 31, 2017, cost of revenues included \$0.6 million of costs related to the write off of inventory related to two presentations of our frozen bag products. For the year ended December 31, 2017, cost of revenues also included an increase in inventory reserves of \$1.5 million of costs related to inventory and raw materials that were expected to expire in less than six months. Consistent with our strategy, we have increased headcount in our production and quality groups to support our growth and expansion into injectable manufacturing. Total employee related costs increased by \$0.3 million, headcount increased from 87 at December 31, 2016 to 117 at December 31, 2017. In addition, our rapid growth has contributed to some production inefficiencies, as we are expanding our manufacturing footprint and capacity in topical manufacturing, and adding sterile manufacturing capabilities at the existing facility. In addition, costs as a percentage of sales increased as revenue from contract services decreased by \$8.0 million as compared to the same period in 2016, and the change in product mix resulted in an increase in costs as a percentage of sales

Selling, general and administrative expenses for the year ended December 31, 2017 increased by \$4.9 million as compared to the same period in 2016. In 2017, there was an increase of \$1.4 million in bad debt expense, \$1.6 million in professional fees primarily related to increased legal costs associated with twelve putative class action lawsuits filed against us along with others regarding pricing of econazole nitrate cream. In addition, there were increases of \$1.3 million in salaries and related costs, \$0.4 million in corporate expenses, \$0.1 million in recruiting fees, \$0.1 million from the issuance of stock-based compensation related to options and restricted stock, \$0.1 million in amortization expense offset by a decrease of \$0.1 million in conferences and seminars.

Product development and research expenses for the year ended December 31, 2017 increased by \$2.1 million as compared to the same period in 2016. Consistent with our strategy to expand our portfolio of generic prescription pharmaceutical products, we increased headcount, which resulted in an increase of \$1.2 million in salaries and related costs, \$0.8 million in clinical studies, \$0.5 million in overhead costs, \$0.1 million related to the impairment of an intangible asset, \$0.1 million in stock based compensation related to options and restricted stock and \$0.1 million in GDUFA and associated fees. These were partially offset by decreases in exhibit and pilot batch costs of \$0.4 million and consulting fees of \$0.3 million,

Interest and Other Expense, net (in thousands):

	Year Ended December 31,		Increase/(Decrease)	
	2017	2016	\$	%
Interest and other expense, net	\$(11,198)	\$(13,304)	\$ 2,106	16 %
Foreign exchange (loss) / gain	\$7,719	\$(936)	\$ 8,655	100 %

Interest expense decreased for the year ended December 31, 2017 as compared to the same period in 2016. The decrease is related to the interest expense, amortization of debt discount and amortization of debt issuance costs of the Notes (see Note 5), partially offset by capitalized interest of \$3.6 million related to our facility expansion. Foreign exchange gain of \$7.7 million was recorded for the year ended December 31, 2017, 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.

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

	Year Ended December 31,		Increase/(Decrease)	
	2017	2016	\$	%
Net loss attributable to common stockholders	\$(15,191)	\$(11,985)	\$ (3,206)	27 %
Basic loss per share	\$(0.28)	\$(0.23)	\$ (0.05)	22 %
Diluted loss per share	\$(0.28)	\$(0.23)	\$ (0.05)	22 %

Net loss for the year ended December 31, 2017 was \$15.2 million as compared to net loss of \$12.0 million for the year ended December 31, 2016. The increase is due to increases in costs and expenses in 2017 offset by foreign currency exchange gain of \$7.7 million.

Fiscal year ended December 31, 2016 compared to fiscal year ended December 31, 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):

43

Edgar Filing: Teligent, Inc. - Form 10-K

Components of Revenue:	Year Ended		Increase/(Decrease)	
	December 31,			
	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		Increase/(Decrease)	
	December 31,			
	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		Increase/(Decrease)	
	December 31,			
	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 5), 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		Increase/(Decrease)	
	December 31,			
	2016	2015	\$	%
Net (loss) income attributable to common stockholders	\$(11,985)	\$6,668	\$(18,653)	(280)%
Basic (loss) earnings 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.

Liquidity and Capital Resources

Our principal sources of liquidity were cash and cash equivalents of approximately \$26.7 million at December 31, 2017 and cash from operations. We had working capital of \$40.4 million at December 31, 2017. 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 or 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 2019.

Our operating activities provided \$0.4 million of cash during the year ended December 31, 2017 compared to \$0.8 million of cash used during the year ended December 31, 2016 and \$15.5 million of cash used during the year ended December 31, 2015. The cash provided for the year ended December 31, 2017 was mostly due to collections of accounts receivable in 2017, which contributed to a net decline in accounts receivable of \$1.9 million, in addition to other changes in operating assets and liabilities, offset by \$5.4 million of interest expense paid in 2017 related to our Notes. The cash provided for the year ended December 31, 2016 was mostly due to the collection of the Canadian goods and services tax (GST) and the harmonized sales tax (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.

Our investing activities used \$40.4 million during the year ended December 31, 2017 compared to \$20.1 million and \$53.1 million of cash used in the years ended December 31, 2016 and December 31, 2015, respectively. The funds used for the year ended December 31, 2017 included \$40.4 million in capital expenditure, the majority of which were for the facility expansion in Buena. The funds used for the year ended December 31, 2016 included \$16.7 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. 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.

Our financing activities provided \$0.3 million of cash during the year ended December 31, 2017 compared to \$10,000 and \$3.1 million of cash used in financing activities in the year ended December 31, 2016 and December 31, 2015, respectively. The cash provided during the year ended December 31, 2017 consisted of proceeds from the exercise of common stock options and warrants. 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.

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.

	Payments Due by Period				
	(in thousands)				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Contractual Obligations					
Convertible Senior Notes	\$ 143,750	\$ —	\$ 143,750	\$ —	\$ —
Operating Lease	2,513	491	877	730	415
Total	\$ 146,263	\$ 491	\$ 144,627	\$ 730	\$ 415

Edgar Filing: Teligent, Inc. - Form 10-K

As of December 31, 2017, our principal outstanding debt obligation related to our Notes is a total of \$143.75 million and are due in December of 2019. The Notes bear interest at a fixed rate of 3.75% per year, payable semi-annually in arrears on June 15 and December 15 each year, until the notes mature on December 15, 2019. At December 31, 2017, we have a future obligation to pay the interest related to these notes of a total amount of \$10.6 million, payable semi-annually in arrears on June 15 and December 15 each year, through December 19, 2019, unless the notes are earlier repurchased, redeemed or converted.

We have certain licensing and development agreement in place under which we will pay certain licensing fees and milestones over the lives of certain projects. These commitments totaled approximately \$2.4 million as of December 31, 2017, and will be paid over the next several years in accordance with agreed upon milestones.

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 and other accrued liabilities at December 31, 2017 approximate their fair value for all periods presented. The Company measures fair value in accordance with ASC 820-10, "Fair Value Measurements and Disclosures". ASC 820-10 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, ASC 820-10 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

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.

We measure our 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, we received approval to increase our 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. We 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, we reclassified the fair value of the derivative liability into stockholders equity due to the approval of sufficient shares. Based on the closing price of our common stock as of December 31, 2017, the net carrying value of the Notes was approximately \$121 million compared to their face value of \$143.75 million as of December 31, 2017. 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 us to interest rate risk.

Accounts Receivable and Allowance for Doubtful Accounts

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

We extend credit to wholesaler and distributor customers and national retail chain customers, based upon credit evaluations, in the normal course of business, primarily with 60 to 90 day terms. We maintain 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 70% 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

We consider 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.

We derive our revenues from three basic types of transactions: sales of our own pharmaceutical products, sales of manufactured product for our 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: We record revenue from Company product sales when title and risk of ownership have been transferred to the customer, which is generally upon shipment of products.

Revenue and Provision for Sales Returns and Allowances

As is customary in the pharmaceutical industry, our gross product sales from Company label products are subject to a variety of deductions in arriving at reported net product sales. When we recognize 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. We 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 us by our wholesale customer for a particular product and the negotiated contract price that the wholesaler's customer pays for that product. Our 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. We 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 our chargeback payments. We continually monitor current pricing trends and wholesaler inventory levels to ensure the liability for future chargebacks is fairly stated.

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

Contract Manufacturing Sales: We recognize revenue when title transfers to our 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 our Consolidated Statement of Operations.

Research and Development Services and Other Income: We establish agreed upon product development agreements with our 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 we have no future performance obligations relating to that phase of development. Revenue recognition requires us 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 us and the customer and are stated in the contracts themselves and do not always align with the revenues recognized.

Derivatives

We account for our 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. We have not entered into hedging activities to date. Our derivative liability was the embedded convertible option of its Notes issued December 16, 2014 (see Note 5), 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 our annual shareholder meeting, the liability for the embedded derivative was reclassified to equity on May 20, 2015. We had no derivatives at December 31, 2017 and December 31, 2016.

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 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, the impairment of long-lived assets (including intangibles, goodwill, and property, plant and equipment), property, plant and equipment and legal accruals for environmental cleanup and remediation costs. Actual results could differ from those estimates.

Adoption of Recent Accounting Pronouncements

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. Our adoption of this ASU, effective January 1, 2017, did not have any significant impact on our consolidated financial statements.

In March 2016, the FASB issued ASU 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. We have adopted this ASU, effective January 1, 2017, and are recognizing windfall tax benefits in additional paid in capital on a prospective basis.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued 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 the Company means January 1, 2019. The Company is currently evaluating the impact of this ASU on its 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 variable interest entity "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 January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805): "Clarifying the Definition of a Business". The update clarifies the definition of a business, specifically for companies to better evaluate whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments in this update are effective for public companies for annual periods beginning after December 15, 2017, including interim periods within those annual periods. For us, the amendments are effective January 1, 2018. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-03, Accounting Changes and Error Corrections (Topic 250) and Investments—Equity Method and Joint Ventures (Topic 323): "Amendments to SEC Paragraphs Pursuant to Staff Announcements at the September 22, 2016 and November 17, 2016 EITF Meetings". The update shows amendments to two SEC Announcements made late in 2016 regarding four specific standards as follows: ASU 2014-09, Revenue from Contracts with Customers (Topic 606), ASU 2016-02, Leases (Topic 842), ASU 2016-13, Financial Instruments - Credit Losses (Topic 326), and ASU 2014-01, Investments - Equity Method and Joint Ventures (Topic 323). The amendments in this update require changes to the U.S. GAAP Financial Reporting Taxonomy and the changes will be incorporated into the proposed 2018 Taxonomy which are available for public comment and finalized as part of the annual release process. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): "Simplifying the Test for Goodwill Impairment". The update simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. It affects public entities that have goodwill reported in their financial statements and have not elected the private company alternative for the subsequent measurement of goodwill. A public entity that is a U.S. Securities and Exchange Commission ("SEC") filer should adopt the amendments in this update for its annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. For us, the amendments are effective January 1, 2020. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In February 2017, the FASB issued ASU 2017-05, Other Income—Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20): "Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets". This update addresses guidance for partial sales of nonfinancial assets. It affects (i) an entity that enters into a contract to transfer to a customer a nonfinancial asset, group of nonfinancial assets, or ownership interest in a consolidated subsidiary that is not a business or nonprofit entity, (ii) an entity that historically had transactions within the scope of the real estate-specific derecognition guidance, and (iii) an entity that contributes nonfinancial assets that are not a business or a nonprofit activity to a joint venture or other noncontrolled investee. The amendments are effective at the same time as the amendments in ASU 2014-09. Therefore, for the Company, the amendments are effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Public entities may apply the guidance earlier but only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We do not currently expect to enter into any such nonfinancial asset or ownership interest in our consolidated subsidiaries agreements but will refer to the guidance in ASU 2017-05 should that occur. We are currently evaluating the impact of this ASU on our consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation—Stock Compensation (Topic 718): “Scope of Modification Accounting”. This update provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718, Compensation—Stock Compensation, to a change to the terms or conditions of a share-based payment award. The amendments affect any entity that changes the terms or conditions of a share-based payment award. The amendments are effective for fiscal years beginning after December 15, 2017. For us, the amendments are effective January 1, 2018. We have not made any changes to the terms or conditions of share-based payment awards but will refer to the guidance in ASU 2017-09 should that occur. Our adoption of this ASU is not expected to have any significant impact on our consolidated financial statements.

In February 2018, the FASB issued ASU 2018-02, “Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income,” which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. This guidance is effective for all entities for fiscal years, and interim periods within those years, beginning after December

15, 2018, with early adoption permitted. The amendments in ASU 2018-02 should be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act is recognized. The adoption of this guidance is not expected to have a material impact on our Consolidated Financial Statements and related disclosures.

Revenue Topic 606 Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)." The standard, including subsequently issued amendments, will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The key focus of the new standard is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this key focus, there is a five-step approach outlined in the standard. Entities are permitted to apply the new standard either retrospectively, subject to certain practical expedients, or the modified retrospective method that requires the application of the guidance only to contracts that are uncompleted on the date of initial application. For us, Topic 606 and subsequently issued amendments will be effective January 1, 2018.

We have performed a comprehensive review of our existing revenue arrangements as of December 31, 2017 following the five-step model. Our analysis indicates that there will be no significant changes to how the amount and timing of revenue will be recognized under the new guidance as compared to existing guidance. Additionally, our analysis indicates that there will be no significant changes to how costs to obtain and fulfill our customer contracts will be recognized under the new guidance as compared to existing guidance. We will adopt this guidance as of January 1, 2018 using the modified retrospective method and we expect that the impact of adoption on our consolidated balance sheet, statement of operations, statement of changes in stockholders' equity and statement of cash flows will not be material. The adoption of the new guidance will impact the way we analyze, document, and disclose revenue recognition under customer contracts beginning on January 1, 2018; will require reclassification of certain amounts on the balance sheet and will result in additional disclosures in our financial statements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2017, 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, 2017, the fair value of our Notes was approximately \$121 million compared to their face value of \$144 million as of December 31, 2017. 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.

Edgar Filing: Teligent, Inc. - Form 10-K

At December 31, 2017, 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

51

(i) Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2017, an evaluation was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act). Based on this evaluation, such officers have concluded that our disclosure controls and procedures were not effective as of December 31, 2017, because of the material weaknesses in our internal control over financial reporting described below.

(ii) Management’s Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). The Company’s internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, 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.

Management, including our Chief Executive Officer and Chief Financial Officer, assessed the Company’s internal control over financial reporting and concluded that they were not effective as of December 31, 2017. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework (2013). Management identified material weaknesses in internal control over financial reporting as of December 31, 2017, as described below.

We identified material weaknesses resulting from the lack of timely and effective review of the Company’s period-end closing process. Specifically, management concluded that the material weakness relates to the Company not having adequate personnel and resources in place for its implementation of a new enterprise-wide financial system (“ERP”). Management evaluated the impact in our assessment of our reporting procedures and has concluded that the control deficiencies represented a material weakness in relation to the Company’s internal controls over financial reporting. Consequently, the same financial reporting personnel were not able to perform a timely and effective review of our period-end closing process.

Additionally, we identified material weaknesses resulting from control deficiencies related to Information Technology General Controls (“ITGC”). Management evaluated the impact in our assessment of our reporting procedures and has concluded that the control deficiencies represented a material weakness in relation to the Company’s internal controls over financial reporting. The factors that contributed to this included the following:

- The absence of a formal policy to assess the adequacy of the design and operating effectiveness of controls related to the Company’s key ERP third party service provider.
- The absence of or breakdown of Information Security, Change Management and System Development Life Cycle controls related to the company’s key financial systems.

On March 12, 2018, after discussions with the Company’s Audit Committee, management concluded that the restatement of the Form 10-Q for the quarter ended September 30, 2017 was necessary. Management concluded that

the material weaknesses related to (i) the ineffective management review, process and controls related to price concessions of a certain product in Canada, specifically, we have inadequate controls to ensure that the information necessary to properly record transactions is adequately communicated on a timely basis from non-financial personnel to those responsible for financial reporting; and (ii) the proper application of accounting guidance and the Company's policy related to the allowance for doubtful accounts.

(iii) Remediation Plan for Material Weaknesses in Internal Control over Financial Reporting
Remediation

To remediate the material weaknesses, the Company has begun to implement new procedures and employ additional resources, including the following:

52

Hiring new team members and engaging external resources with significant prior experience with systems similar to the Company's new ERP system to provide additional capacity, analytical and functional capabilities, and cross-training.

Implementing business process improvements, that are anticipated to both strengthen controls governing management review and approvals and enable a more efficient and effective month end close.

Conducting regular reviews of all information system access to validate that access is appropriate and appropriate segregation of duties exist.

Recruiting a new senior leader in one of its foreign affiliates who, among other responsibilities, will ensure

- customer contract terms are reviewed with key members of the Finance Department on a timely basis to ensure customer price concessions are reflected appropriately in the financial records.

Establishing formal policies and procedures for the accounting and internal audit function.

Developing policies and procedures addressing the internal control framework of the Company's ERP service provider.

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 Exhibits 10.31 and 10.32 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 2018 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 2018 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 2018 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 2018 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 2018 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 19, 2009 8-K).

54

- (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 Quarterly Report on Form 10-Q/A, 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 SARI (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 SARI (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. (incorporated by reference to Exhibit 10.31 to the Company 10-K, filed March 12, 2017).
- (10.32)# Form of Amendment to Outstanding RSU Agreements under the Company's 2009 Equity Incentive Plan. (incorporated by reference to Exhibit 10.32 to the Company 10-K, filed March 12, 2017).
- (21) List of Subsidiaries (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 10-K, filed March 16, 2017).
- (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, 2017, 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.

56

*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.

57

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 19, 2018

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 19, 2018
/s/ Damian Finio Damian Finio	Chief Financial Officer (Principal Financial Officer)	March 19, 2018
/s/ Steven Koehler Steven Koehler	Director	March 19, 2018
/s/ James Gale James Gale	Director	March 19, 2018
/s/ Bhaskar Chaudhuri Bhaskar Chaudhuri	Director	March 19, 2018
/s/ John Celentano John Celentano	Director	March 19, 2018
/s/ Carole Ben-Maimon Carole Ben-Maimon	Director	March 19, 2018
/s/ Thomas Sabatino Thomas Sabatino	Director	March 19, 2018

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

<u>Reports of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2017 and 2016</u>	F-5
<u>Consolidated Statements of Operations for the years ended December 31, 2017, 2016 and 2015</u>	F-6
<u>Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2017, 2016 and 2015</u>	F-7
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2017, 2016 and 2015</u>	F-8
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2017, 2016 and 2015</u>	F-9
<u>Notes to Consolidated Financial Statements</u>	F-10
<u>Financial Statement Schedule: Quarterly Results (Unaudited)</u>	F-35
<u>Financial Statement Schedule: Schedule II - Valuation and Qualifying Accounts</u>	F-36

F-1

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Teligent, Inc. and subsidiaries (the "Company") as of December 31, 2017 and 2016, 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, 2017 and the related notes and schedule II (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2017 and 2016, and the consolidated results of their operations and their cash flows for each of years in the three-year period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated March 19, 2018 expressed an adverse opinion.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EISNERAMPER LLP

We have served as the Company's auditor since August 2010.

Iselin, New Jersey
March 19, 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Internal Control over Financial Reporting

We have audited Teligent, Inc. and Subsidiaries' (the "Company") internal control over financial reporting as of December 31, 2017, based on criteria established in the 2013 Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, Teligent, Inc. and Subsidiaries has not maintained effective internal control over financial reporting as of December 31, 2017, based on criteria established in the Internal Control - Integrated Framework (2013) issued by COSO.

A material weakness is a control deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment.

- (i) a lack of timely and effective review of the Company's period-end closing process due to the Company not having adequate personnel and resources in place for its implementation of the new enterprise-wide financial system;
- (ii) an aggregation of control deficiencies related to the Company's information technology general controls;
- (iii) an ineffective management review of the process and controls over price concessions in Canada and;
- (iv) the proper application of accounting guidance and the Company's policy related to the allowance for doubtful accounts.

These material weaknesses were considered in determining the nature, timing, and extent of the audit tests applied in our audit of the December 31, 2017 financial statements, and this report does not affect our report dated March 19, 2018, on those financial statements.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of Teligent, Inc. and Subsidiaries as of December 31, 2017 and 2016, 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, 2017, and the related notes and schedules, and our report dated March 19, 2018 expressed an unqualified opinion.

Basis for Opinion

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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

F-3

Definition and Limitations of Internal Control over Financial Reporting

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.

/s/ EISNERAMPER LLP

Iselin, New Jersey
March 19, 2018

F-4

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

	December 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$26,692	\$66,006
Accounts receivable, net	18,143	21,735
Inventories	16,075	12,708
Prepaid expenses and other receivables	3,622	2,847
Total current assets	64,532	103,296
Property, plant and equipment, net	68,355	26,215
Intangible assets, net	56,017	52,465
Goodwill	471	446
Other	611	804
Total assets	\$189,986	\$183,226
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$10,595	\$4,614
Accrued expenses	13,502	10,349
Total current liabilities	24,097	14,963
Convertible 3.75% senior notes, net of debt discount and debt issuance costs (face of \$143,750)	120,977	111,391
Deferred tax liability	159	205
Total liabilities	145,233	126,559
Stockholders' equity:		
Common stock, \$0.01 par value, 100,000,000 shares authorized; 53,400,281 and 53,148,441 shares issued and outstanding as of December 31, 2017 and December 31, 2016, respectively	554	551
Additional paid-in capital	106,312	102,624
Accumulated deficit	(60,094)	(44,903)
Accumulated other comprehensive loss, net of taxes	(2,019)	(1,605)
Total stockholders' equity	44,753	56,667
Total liabilities and stockholders' equity	\$189,986	\$183,226

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

TELIGENT, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
For the years ended December 31, 2017, 2016 and 2015
(in thousands, except shares and per share information)

	2017	2016	2015
Components of Revenue:			
Product sales, net	\$ 66,999	\$ 65,904	\$ 43,497
Research and development services and other income	252	977	753
Total revenues	67,251	66,881	44,250
Costs and Expenses:			
Cost of revenues	39,879	32,194	22,935
Selling, general and administrative expenses	19,904	15,005	11,336
Product development and research expenses	19,265	17,140	13,171
Total costs and expenses	79,048	64,339	47,442
Operating (loss) income	(11,797)	2,542	(3,192)
Other Income (Expense):			
Change in the fair value of derivative liability	—	—	23,144
Foreign currency exchange gain (loss)	7,719	(936)	109
Interest and other expense, net	(11,198)	(13,304)	(13,358)
(Loss) income before income tax expense	(15,276)	(11,698)	6,703
Income tax (benefit) expense	(85)	287	35
Net (loss) income attributable to common stockholders	\$ (15,191)	\$ (11,985)	\$ 6,668
Basic (loss) earnings per share	\$ (0.28)	\$ (0.23)	\$ 0.13
Diluted (loss) earnings per share	\$ (0.28)	\$ (0.23)	\$ (0.07)
Weighted average shares of common stock outstanding:			
Basic	53,323,954	53,078,158	52,872,814
Diluted	53,323,954	53,078,158	67,111,995

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, 2017, 2016 and 2015
 (in thousands)

	2017	2016	2015
Net income (loss)	\$(15,191)	\$(11,985)	\$6,668
Other comprehensive loss, net of tax			
Foreign currency translation adjustment	(414)	(1,475)	(130)
Other comprehensive loss	(414)	(1,475)	(130)
Comprehensive income (loss)	\$(15,605)	\$(13,460)	\$6,538

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

F-7

TELIGENT, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended December 31, 2017, 2016 and 2015

	2017	2016	2015
Cash flows from operating activities:			
Net income (loss)	\$(15,191)	\$(11,985)	\$6,668
Reconciliation of net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization of fixed assets	1,711	946	560
Amortization of license fee	—	—	100
Provision for write down of inventory	2,132	1,400	50
Provision for bad debt	1,767	327	—
Issuance of stock to consultant	—	189	—
Stock based compensation	3,295	2,999	2,273
Amortization of debt issuance costs	943	828	1,132
Amortization of intangibles	2,930	2,833	514
Foreign currency exchange loss (gain)	(7,719)) 936	(109)
Amortization of debt discount on convertible 3.75% senior notes	8,643	7,599	6,680
Change in the fair value of derivative liability	—	—	(23,144)
Loss on disposal of property/impairment	113	16	—
Changes in operating assets and liabilities:			
Accounts receivable	1,894	(8,008)) 1,250
Inventories	(5,275)) (5,042)) (3,578)
Prepaid expenses and other current receivables	(748)) 3,427	(5,408)
Other assets	194	316	(14)
Accounts payable and accrued expenses	5,711	2,897	(2,849)
Deferred income	—	(476)) 362
Net cash provided by (used in) operating activities	400	(798)) (15,513)
Cash flows from investing activities:			
Capital expenditures	(40,429)) (16,655)) (5,998)
Acquisition of product rights and other related assets	—	—	(35,418)
Product acquisition costs, net	—	(3,421)) (11,652)
Net cash used in investing activities	(40,429)) (20,076)) (53,068)
Cash flows from financing activities:			
Proceeds from issuance of stock, net	—	—	(3)
Principal payments on note payable, bank	—	—	(3,160)
Proceeds from exercise of common stock options and warrants	269	96	165
Principal payments on capital lease obligations	—	(70)) (132)
Payment (recovery) from stockholder, net	—	(36)) 19
Net cash provided by (used in) financing activities	269	(10)) (3,111)
Effect of exchange rate on cash and cash equivalents	446	(301)) —
Net decrease in cash and cash equivalents	(39,760)) (20,884)) (71,692)
Cash and cash equivalents at beginning of year	66,006	87,191	158,883
Cash and cash equivalents at end of year	\$26,692	\$66,006	\$87,191

Supplemental Cash flow information:

Cash payments for interest	\$5,391	\$5,393	\$5,517
Cash payments for income taxes	126	113	123
Non cash investing and financing transactions:			
Reclassification of derivative liability to equity	—	—	18,256
Acquisition of capital expenditures in accounts payable and accrued expenses	3,186	1,805	—
Capitalized stock compensation in capital expenditures	127	91	—
Issuance of stock to consultant	—	189	31
Issuance of restricted stock	—	—	347

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

F-8

TELIGENT, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the years ended December 31, 2017, 2016 and 2015
(in thousands, except share information)

	Series A Convertible Preferred Stock Shares	Series C Convertible Preferred Stock Shares	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	
Balance, December 31, 2014	—	—	—	\$ 52,819,787	\$ 548	\$ 78,172	\$(39,586)	\$ —	\$ 39,134
Issuance of stock pursuant to a public offering, net of associated fees of \$1,868									—
Issuance of stock to consultant			5,000		31				31
Stock based compensation expense					2,273				2,273
Stock warrants exercised			67,636		82				82
Stock options exercised			75,766	1	82				83
Issuance of restricted stock			32,500		346				346
Reclassification of derivative liability to equity					18,256				18,256
Recovery from stockholder, net					19				19
Costs related to stock issuance					(3)				(3)
Cumulative translation adjustment							(130)		(130)
Net income	—	—	—	—	—	6,668	—		6,668
Balance, December 31, 2015	—	—	—	\$ 53,000,689	\$ 549	\$ 99,258	\$(32,918)	\$(130)	\$ 66,759
Issuance of stock to consultant			25,000		189				189
Stock based compensation expense					3,090				3,090
Stock warrants exercised									—
Stock options exercised			61,834	1	95				96
Issuance of stock for vested restricted stock units			60,918	1					1
Recovery from stockholder, net					(36)				(36)
Tax benefit related to stock options					28				28
Cumulative translation adjustment							(1,475)		(1,475)
Net loss	—	—	—	—	—	(11,985)	—		(11,985)

Edgar Filing: Teligent, Inc. - Form 10-K

Balance, December 31, 2016	—	—	—	\$	—53,148,441	\$ 551	\$102,624	\$ (44,903)	\$ (1,605)	\$ 56,667
Issuance of stock to consultant										—
Stock based compensation expense							3,422			3,422
Stock options exercised					171,566	2	267			269
Issuance of stock for vested restricted stock units					80,274	1	(1)			—
Cumulative translation adjustment									(414)	(414)
Net loss	—	—	—	—	—	—	—	(15,191)	—	(15,191)
Balance, December 31, 2017	—	—	—	\$	—53,400,281	\$ 554	\$106,312	\$ (60,094)	\$ (2,019)	\$ 44,753

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

F-9

TELIGENT, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Liquidity

Nature of the Business

Teligent, Inc. is a Delaware corporation incorporated in 1977 and is a specialty generic pharmaceutical company. Under its own label, the Company markets and sells generic topical and branded generic and generic injectable pharmaceutical products in the United States and Canada. In the United States, the Company currently markets 25 generic topical pharmaceutical products and four branded generic pharmaceutical products. In Canada, the Company sells over 30 generic and branded generic injectable products and medical devices. Generic pharmaceutical products are bioequivalent to their brand name counterparts. The Company also provides contract manufacturing services to the pharmaceutical, over-the-counter, ("OTC"), and cosmetic markets. The Company operates its business under one segment. Our common stock is trading on the NASDAQ Global Select Market, under the trading symbol "TLGT."

Teligent also develops, manufactures, fills, and packages topical semi-solid and liquid products for branded and generic pharmaceutical customers, as well as the OTC and cosmetic markets. These products are used in a wide range of applications from cosmetics and cosmeceuticals to the prescription treatment of conditions like dermatitis, psoriasis, and eczema. Teligent has continued to make progress on its facility expansion in Buena, New Jersey, to support the increased capacity demand expected from future product approvals from the FDA. As the Company continues to execute the expansion of our development and commercial base beyond topical generics to include injectable generics, complex generics and ophthalmic generics (what we call our "TICO strategy"), it will compete in other markets, including the ophthalmic generic pharmaceutical market, and expects to face other competitors.

Liquidity

The Company's principal sources of liquidity are cash and cash equivalents of approximately \$26.7 million at December 31, 2017 and cash from operations. The Company may require additional funding and this funding will depend, in part, on the timing and structure of potential business arrangements. If necessary, the Company may continue to seek to raise additional capital through the sale of its equity or through a strategic alliance with a third party. There may also be additional acquisition and growth opportunities that may require external financing. There can be no assurance that such financing will be available on terms acceptable to the Company, or at all. The Company also has the ability to defer certain product development and other programs, if necessary. The Company believes that our existing capital resources will be sufficient to support its current business plan and operations beyond March 2019.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Teligent, Inc. and its wholly-owned and majority-owned subsidiaries. All inter-company accounts and transactions have been eliminated. The Company consolidated the following entities: Igen, Inc., Teligent Pharma, Inc., Teligent Luxembourg S.à.r.l., Teligent OÜ, Teligent Canada Inc., and Teligent Jersey Limited., in addition to the following inactive entities: Microburst Energy, Inc., Blood Cells, Inc. and Flavorsome, Ltd.

Cash Equivalents

Cash equivalents include cash on hand and money market funds. The carrying amounts approximate the fair value due to the short term maturity of these investments. Money market funds are short-term investments, which have original maturities of 90 days or less. These include direct obligations of the U.S. Treasury, including bills, notes and bonds, as well as obligations issued or guaranteed by agencies or instrumentalities of the U.S. government including government-sponsored enterprises, or GSEs.

The Company has restricted cash, consisting of escrow accounts (see Note 12) and letter of credits, totaling \$0.5 million as of December 31, 2017 and December 31, 2016. These balances are included within Other Assets on the Consolidated Balance Sheet.

Fair Value of Financial Instruments

F-10

The carrying amounts of cash and cash equivalents, trade receivables, restricted cash, notes payable, accounts payable and other accrued liabilities at December 31, 2017 approximate their fair value for all periods presented.

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

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.

Accounts Receivable and Allowance for Doubtful Accounts

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

The Company extends credit to wholesaler and distributor customers and national retail chain customers, based upon credit evaluations, in the normal course of business, primarily with 60 to 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 70% of the gross sales through this distribution channel. Certain of these accruals and allowances are recorded in the balance sheet as current liabilities and others are recorded as a reduction to accounts receivable.

Revenue Recognition

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

The Company derives its revenues from three basic types of transactions: sales of its own generic pharmaceutical topical products, sales of manufactured product for its customers included in product sales, and research and product development services 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 ("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,

F-11

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.

Accounts receivable are presented net of SRA balances of \$28.5 million and \$41.5 million at December 31, 2017 and 2016, respectively. Accounts payable and accrued expenses include \$7.0 million and 3.5 million at December 31, 2017 and 2016, respectively, for certain fees related to services provided by the wholesalers. Wholesale fees of \$7.0 million, \$3.7 million and \$6.3 million for the years ended December 31, 2017, 2016 and 2015, respectively, were included in cost of goods sold.

In addition, in connection with four of the 29 products the Company currently manufactures, markets and distributes in its own label in the U.S., in accordance with an agreement entered into in December of 2011, the Company is required to pay a royalty calculated based on net sales to one of its pharmaceutical partners. The royalty is calculated based on contracted terms of 40% of net sales for the four products, which is to be paid quarterly to the pharmaceutical partner that the agreement is with. In accordance with the agreement, net sales exclude fees related to services provided by the wholesalers. Accounts payable and accrued expenses include \$0.9 million and \$0.8 million at December 31, 2017 and 2016, respectively, related to these royalties. Royalty expense of \$2.2 million, \$3.0 million and \$3.6 million was included in cost of goods sold for the years ended December 31, 2017, 2016, and 2015 respectively. The Company includes significant estimates to arrive at net product sales arising from wholesaler chargebacks, Medicaid and Medicare rebates, allowances and other pricing and promotional programs.

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 and are included in product sales, net on the Company's Consolidated Statement of Operations.

Research and Development Income: The Company establishes agreed upon product development agreements with its customers to perform product development services. Product development revenues are recognized in accordance with

the product development agreement upon the completion of the phases of development and when the Company has no future performance obligations relating to that phase of development. Revenue recognition requires the Company to assess progress against contracted obligations to assure completion of each stage. These payments are generally non-refundable and are reported as deferred until they are recognizable as revenue. If no such arrangement exists, product development fees are recognized ratably over the entire period during which the services are performed. 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.

Concentration of Risk

F-12

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

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

In 2017, the Company had sales to three customers which individually accounted for more than 10% of the Company's total revenue. These customers had sales of \$18.7 million, \$9.9 million and \$9.6 million, respectively, and represented 57% of total revenues in the aggregate. Accounts receivable related to the Company's major customers comprised of 47%, 15% and 14%, respectively, and represented 76% of all accounts receivable as of December 31, 2017. In 2016, the Company had sales to three customers which individually accounted for more than 10% of the Company's total revenue. These customers had sales of \$13.5 million, \$8.6 million and \$6.8 million, respectively, and represented 43% of total revenues in the aggregate. Accounts receivable related to the Company's major customers comprised of 20%, 56% and 11%, respectively, and represented 81% of all accounts receivable as of December 31, 2016. In 2015, the Company had sales to three customers which individually accounted for more than 10% of the Company's total revenue. These customers had sales of \$12.3 million and \$5.8 million and \$6.5 million, respectively, and represented 52% of total revenues in the aggregate. Accounts receivable related to the Company's major customers comprised of 43%, 33% and 6%, respectively, and represented 83% of all accounts receivable as of December 31, 2015.

The Company had net revenue from one product, Econazole Nitrate Cream 1%, which accounted for 4%, 8%, and 45% of total revenues in 2017, 2016 and 2015, respectively. Lidocaine Ointment 5%, which the Company launched at the end of the first quarter of 2016 accounted for 17% and 23% of total revenues in 2017 and 2016. Zantac for injection, which the Company acquired in the fourth quarter of 2015, accounted for 10%, 3% and 0% of total revenues in 2017, 2016 and 2015.

For the year ended December 31, 2017, domestic net revenues were \$53.5 million and foreign net revenues were \$13.8 million. As of December 31, 2017, domestic assets were \$117.7 million and foreign assets were \$72.3 million. 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 assets were \$120.0 million and foreign assets were \$63.2 million. For the year ended December 31, 2015, domestic net revenues were \$42.7 million and foreign net revenues were \$1.6 million. As of December 31, 2015, domestic assets were \$129.0 million and foreign assets were \$51.7 million.

While the company purchases raw materials to manufacture certain products, it also utilizes contract manufacturing organizations (CMO's) to purchase finished products. The Company currently purchases from numerous sources which therefore reduces the risk of delays or difficulties in getting materials and/or products.

Inventories

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

Property, Plant and Equipment

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

	Useful Lives
Buildings and improvements	10 - 40 years
Machinery and equipment	5 - 15 years
Computer hardware and software	3 - 5 years
Furniture and fixtures	5 years

F-13

Leasehold improvements are amortized over the shorter of estimated useful life or the lease term. Repair and maintenance costs are charged to operations as incurred while major improvements are capitalized. Construction in progress ("CIP") costs are amortized based on the asset class when they are put into service. When assets are retired or disposed, the related cost and accumulated depreciation thereon are removed and any gains or losses are included in operating results.

Intangible Assets

Definite-lived intangible assets are stated at cost less accumulated amortization. Amortization of definite-lived intangible assets is computed on a straight-line basis over the assets' estimated useful lives, generally for periods ranging from 10 to 15 years. The Company continually evaluates the reasonableness of the useful lives of these assets. Indefinite-lived intangible assets are not amortized, but instead are tested at least annually for impairment. Costs to renew or extend the term of a recognized intangible asset are expensed as incurred. An impairment is recognized in the amount, if any, by which the carrying amount of such assets exceeds their respective fair values and would be recorded in the selling, general and administrative expense on the Consolidated Statements of Operations.

In-Process Research and Development

Amounts allocated to in-process research and development ("IPR&D") in connection with a business combination are recorded at fair value and are considered indefinite-lived intangible assets subject to the impairment testing in accordance with the Company's impairment testing policy for indefinite-lived intangible assets. As products in development are approved for sale, amounts will be allocated to product rights and will be amortized over their estimated useful lives. These valuations reflect, among other things, the impact of changes to the development programs, the projected development and regulatory time frames and the current competitive environment. Changes in any of the Company's assumptions may result in a reduction to the estimated fair value of the IPR&D asset and could result in future impairment charges.

Long-Lived Assets

In accordance with the provisions of ASC 360-10-55, the Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. In performing such review for recoverability, the Company compares expected future cash flows of assets to the carrying value of the long-lived assets and related identifiable intangibles. If the expected future cash flows (undiscounted) are less than the carrying amount of such assets, the Company recognizes an impairment loss for the difference between the carrying value of the assets and their estimated fair value, with fair values being determined using projected discounted cash flows at the lowest level of cash flows identifiable in relation to the assets being reviewed. As of December 31, 2017, no impairments existed.

Goodwill

Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is tested for impairment on an annual basis during the fourth quarter of each fiscal year or more frequently if events or changes in circumstances indicate that the asset might be impaired. The Company first performs a qualitative assessment to determine if the quantitative impairment test is required. If changes in circumstances indicate an asset may be impaired, the Company performs the quantitative impairment test. In accordance with accounting standards, a two-step quantitative method is used for determining goodwill impairment. In the first step, the Company determines the fair value. If the net book value exceeds its fair value, the second step of the impairment test which requires allocation of the fair value to all of its assets and liabilities using the acquisition method prescribed under authoritative guidance for business combinations would then be performed. Any residual fair value is allocated to

goodwill. An impairment charge is recognized only if the implied fair value of our reporting unit's goodwill is less than its carrying amount.

The carrying value of goodwill at December 31, 2017 was \$0.5 million. We believe it is unlikely that there will be a material change in the future estimates or assumptions used to test for impairment losses on goodwill. However, if actual results were not consistent with our estimates or assumptions, we could be exposed to an impairment charge.

Acquisitions

The Company accounts for acquired businesses using the acquisition method of accounting, which requires with limited exceptions, that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the assigned values of the net assets acquired is recorded as goodwill. When net assets that do not constitute a business are acquired, no goodwill is recognized.

Contingent consideration, if any, is included as part of the acquisition cost and is recognized at fair value as of the acquisition date. Any liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved. These changes in fair value are recognized in earnings.

Foreign Currency Translation

The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recorded in the foreign currency translation account, which is included in accumulated other comprehensive income (loss) (AOCI) and reflected as a separate component of equity. For those subsidiaries where the U.S. dollar has been determined to be the functional currency, non-monetary foreign currency assets and liabilities are translated using historical rates, while monetary assets and liabilities are translated at current rates, with the U.S. dollar effects of rate changes included in Other (income) expense, net.

Foreign exchange gain of \$7.7 million was recorded for the year ended December 31, 2017, 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.

Accounting for Environmental Costs

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

Income Taxes

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

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

Stock-Based Compensation

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

Debt Issuance Costs

F-15

Expenses related to debt financing activities are capitalized and amortized on an effective interest method, over the term of the loan. For more details, refer to Note 5.

ASU 2015-3 specifies that debt issuance costs are to be netted against the carrying value of the financial liability. Under prior guidance, debt issuance costs were recognized as a deferred charge and reported as a separate asset on the balance sheet. The updated guidance aligns the treatment of debt issuance costs and debt discounts in that both reduce the carrying value of the liability. Amortization of debt issuance costs is to be recorded as interest expense on the income statement.

Product Development and Research

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

Shipping and Handling Costs

Costs related to shipping and handling is comprised of outbound freight and the associated labor. These costs are recorded in costs of sales. For the years ended December 31, 2017, 2016 and 2015, the costs relating to shipping and handling totaled \$1.2 million, \$0.7 million and \$0.2 million, respectively.

Earnings (Loss) per Common Share

Basic earnings (loss) per share of common stock is computed based on the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share of common stock is computed using the weighted average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period. Potential dilutive common stock equivalents include shares issuable upon the conversion of the notes and the exercise of options and warrants. Due to the net loss for the years ended December 31, 2017 and 2016, the effect of the Company's potential dilutive common stock equivalents was anti-dilutive; as a result, the basic and diluted weighted average number of common shares outstanding and net loss per common share are the same. As of December 31, 2017, the shares of common stock issuable in connection with stock options and warrants have been excluded from the diluted earnings (loss) per share, as their effect would have been anti-dilutive.

For the years ended December 31, 2017, 2016 and 2015
(in thousands except shares and per share data)

	2017	2016	2015
Basic earnings (loss) per share computation:			
Net income (loss) attributable to common stockholders —basic	\$ (15,191)	\$ (11,985)	\$ 6,668
Weighted average common shares —basic	53,323,954	53,078,158	52,872,814
Basic earnings (loss) per share	\$ (0.28)	\$ (0.23)	\$ 0.13
Dilutive earnings (loss) per share computation:			
Net income (loss) attributable to common stockholders —basic	\$ (15,191)	\$ (11,985)	\$ 6,668
Interest expense related to convertible 3.75% senior notes	—	—	5,391
Amortization of discount related to convertible 3.75% senior notes	—	\$ —	\$ 6,680
Change in the fair value of derivative	—	\$ —	\$ (23,144)
Net loss attributable to common stockholders —diluted	\$ (15,191)	\$ (11,985)	\$ (4,405)
Share Computation:			
Weighted average common shares —basic	53,323,954	53,078,158	52,872,814
Effect of convertible 3.75% senior notes	—	—	12,732,168
Effect of dilutive stock options and warrants	—	—	1,507,013

Edgar Filing: Teligent, Inc. - Form 10-K

Weighted average common shares outstanding —diluted	53,323,954	53,078,158	67,111,995
Diluted net loss per share	\$(0.28)	\$(0.23)	\$(0.07)

Derivatives

The Company accounts for its derivative instruments in accordance with ASC 815-10, “Derivatives and Hedging” (“ASC 815-10”). ASC 815-10 establishes accounting and reporting standards requiring that derivative instruments, including derivative instruments embedded in other contracts, be recorded on the balance sheet as either an asset or liability measured at its fair value. ASC 815-10

F-16

also requires that changes in the fair value of derivative instruments be recognized currently in results of operations unless specific hedge accounting criteria are met. The Company has not entered into hedging activities to date. The Company's derivative liability is the embedded convertible option of its Convertible Notes issued December 16, 2014 (as defined in Note 5), 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 had no derivatives at December 31, 2017 and December 31, 2016.

Use of Estimates

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

Reclassification

Certain prior year amounts were reclassified to conform to current year presentation. For the year ended December 31, 2016, the impact of such reclassification of the non-cash portion of the capital expenditures would have been a reduction of both cash from operating activities and cash used in investing activities, in the amount of \$1.9 million.

Adoption of Recent Accounting Pronouncements

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. The Company's adoption of this ASU, effective January 1, 2017, did not have any significant impact on its consolidated financial statements.

In March 2016, the FASB issued ASU 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. The Company has adopted this ASU, effective January 1, 2017, and is recognizing windfall tax benefits in additional paid in capital on a prospective basis.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued 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 the Company means January 1, 2019. The Company is currently evaluating the impact of this ASU on its 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 variable interest entity "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 the Company, the amendments are effective January 1, 2018. The Company is currently evaluating the impact of this ASU on its consolidated financial statements.

F-17

In January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805): “Clarifying the Definition of a Business”. The update clarifies the definition of a business, specifically for companies to better evaluate whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments in this update are effective for public companies for annual periods beginning after December 15, 2017, including interim periods within those annual periods. For the Company, the amendments are effective January 1, 2018. The Company's adoption of this ASU, is not expected to have any significant impact on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-03, Accounting Changes and Error Corrections (Topic 250) and Investments—Equity Method and Joint Ventures (Topic 323): “Amendments to SEC Paragraphs Pursuant to Staff Announcements at the September 22, 2016 and November 17, 2016 EITF Meetings”. The update shows amendments to two SEC Announcements made late in 2016 regarding four specific standards as follows: ASU 2014-09, Revenue from Contracts with Customers (Topic 606), ASU 2016-02, Leases (Topic 842), ASU 2016-13, Financial Instruments - Credit Losses (Topic 326), and ASU 2014-01, Investments - Equity Method and Joint Ventures (Topic 323). The amendments in this update require changes to the U.S. GAAP Financial Reporting Taxonomy and the changes will be incorporated into the proposed 2018 Taxonomy which are available for public comment and finalized as part of the annual release process. The Company is currently evaluating the impact of this ASU on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): “Simplifying the Test for Goodwill Impairment”. The update simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. It affects public entities that have goodwill reported in their financial statements and have not elected the private company alternative for the subsequent measurement of goodwill. A public entity that is a U.S. Securities and Exchange Commission ("SEC") filer should adopt the amendments in this update for its annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. For the Company, the amendments are effective January 1, 2020. The Company is currently evaluating the impact of this ASU on its consolidated financial statements.

In February 2017, the FASB issued ASU 2017-05, Other Income—Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20): “Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets”. This update addresses guidance for partial sales of nonfinancial assets. It affects (i) an entity that enters into a contract to transfer to a customer a nonfinancial asset, group of nonfinancial assets, or ownership interest in a consolidated subsidiary that is not a business or nonprofit entity, (ii) an entity that historically had transactions within the scope of the real estate-specific derecognition guidance, and (iii) an entity that contributes nonfinancial assets that are not a business or a nonprofit activity to a joint venture or other noncontrolled investee. The amendments are effective at the same time as the amendments in ASU 2014-09. Therefore, for the Company, the amendments are effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Public entities may apply the guidance earlier but only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company does not currently expect to enter into any such nonfinancial asset or ownership interest in its consolidated subsidiaries agreements but will refer to the guidance in ASU 2017-05 should that occur.

In May 2017, the FASB issued ASU 2017-09, Compensation—Stock Compensation (Topic 718): “Scope of Modification Accounting”. This update provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718, Compensation—Stock Compensation, to a change to the terms or conditions of a share-based payment award. The amendments affect any entity that changes the terms or conditions of a share-based payment award. The amendments are effective for fiscal years beginning after December 15, 2017. For the Company, the amendments are effective January 1, 2018. The Company has not made

any changes to the terms or conditions of share-based payment awards but will refer to the guidance in ASU 2017-09 should that occur. The Company's adoption of this ASU is not expected to have any significant impact on its consolidated financial statements.

In February 2018, the FASB issued ASU 2018-02, "Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income," which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. This guidance is effective for all entities for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. The amendments in ASU 2018-02 should be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act is recognized. The adoption of this guidance is not expected to have a material impact on the Company's Consolidated Financial Statements and related disclosures.

Revenue Topic 606 Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)." The standard, including subsequently issued amendments, will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The key focus of the new standard is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this key focus, there is a five-step approach outlined in the standard. Entities are permitted to apply the new standard either retrospectively, subject to certain practical expedients, or the modified retrospective method that requires the application of the guidance only to contracts that are uncompleted on the date of initial application. For the Company, Topic 606 and subsequently issued amendments will be effective January 1, 2018.

We have performed a comprehensive review of our existing revenue arrangements as of December 31, 2017 following the five-step model. Our analysis indicates that there will be no significant changes to how the amount and timing of revenue will be recognized under the new guidance as compared to existing guidance. Additionally, our analysis indicates that there will be no significant changes to how costs to obtain and fulfill our customer contracts will be recognized under the new guidance as compared to existing guidance. We will adopt this guidance as of January 1, 2018 using the modified retrospective method and we expect that the impact of adoption on our consolidated balance sheet, statement of operations, statement of changes in stockholders' equity and statement of cash flows will not be material. The adoption of the new guidance will impact the way we analyze, document, and disclose revenue recognition under customer contracts beginning on January 1, 2018; will require reclassification of certain amounts on the balance sheet and will result in additional disclosures in our financial statements.

3. Inventories

Inventories as of December 31, 2017 and 2016 consisted of:

	2017	2016
	(in thousands)	
Raw materials	\$8,231	\$6,834
Work in progress	616	—
Finished goods	8,532	6,284
Reserve for obsolescence	(1,304)	(410)
	\$16,075	\$12,708

4. Property, Plant and Equipment

Property, plant and equipment, at cost, as of December 31, 2017 and 2016, consisted of:

	2017	2016
	(in thousands)	
Land	\$257	\$257
Building and improvements	8,613	8,515
Machinery and equipment	9,142	7,515
Computer hardware and software	3,244	724
Furniture and fixtures	449	344
Construction in progress	55,017	15,496
	76,722	32,851
Less accumulated depreciation and amortization	(8,367)	(6,636)
Property, plant and equipment, net	\$68,355	\$26,215

The Company recorded depreciation and amortization expense of \$1.7 million, \$0.9 million and \$0.6 million in 2017, 2016 and 2015, respectively. During the twelve months ended December 31, 2017 and 2016 there was \$3.6 million of interest and \$0.4 million of interest, respectively, capitalized into construction in progress. During the twelve months ended December 31, 2017 and 2016 there was \$0.8 million of payroll and \$0.4 million of payroll, respectively, capitalized into construction in progress.

5. Convertible 3.75% Senior Notes

On December 16, 2014, the Company issued \$125 million aggregate principal amount of 3.75% Convertible Senior Notes due 2019, or the Notes. On December 22, 2014, the Company announced the closing of the initial purchasers' exercise in full of their option to purchase an additional \$18.75 million aggregate principal amount. The Notes bear interest at a fixed rate of 3.75% per year, payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2015 and mature on December 15, 2019, unless earlier repurchased, redeemed or converted. The Notes are convertible into shares of the Company's common stock, cash or a combination thereof. On May 20, 2015, the Company received shareholder approval for the increase in the number of shares of common stock authorized and available for issuance upon conversion of the Notes.

The remaining unamortized discount and unamortized debt financing costs will be amortized over the remaining term of the debt of 2.0 years. At December 31, 2017 and December 31, 2016, the net carrying amount of the liability component and the remaining unamortized debt discount were as follows:

Edgar Filing: Teligent, Inc. - Form 10-K

	December 31, 2017 (in thousands)	December 31, 2016 (in thousands)
Face amount of the Notes	\$ 143,750	\$ 143,750
Unamortized discount	20,517	29,160
Debt issuance costs	2,256	3,199
Carrying amount of the Notes	\$ 120,977	\$ 111,391

Debt issuance costs associated with the Notes, include fees of \$2.3 million at December 31, 2017 and \$3.2 million at December 31, 2016.

For the years ended December 31, 2017, December 31, 2016 and December 31, 2015, the Company recorded the following expenses in relation to the Notes:

	December 31, 2017 (in thousands)	December 31, 2016 (in thousands)	December 31, 2015 (in thousands)
Interest Expense at 3.75% coupon rate	\$ 5,391	\$ 5,391	\$ 5,391
Debt discount amortization	8,643	7,599	6,680
Amortization of deferred financing costs	942	828	728
Less: capitalized interest and other	(3,778)) (514) 559
Total interest expense	\$ 11,198	\$ 13,304	\$ 13,358

6. Gross-to-Net

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. The Company's gross-to-net adjustments for the three years ended December 31, 2017, 2016 and 2015 are as follows (in thousands):

	Years ended December 31,		
	2017	2016	2015
Gross product sales	\$215,883	\$217,633	\$99,721
Reduction to gross product sales:			
Chargebacks and billbacks	125,159	141,343	50,127
Sales discounts and other allowances	32,720	27,419	17,974
Total reduction to gross product sales	\$157,879	\$168,762	\$68,101
Product sales, net	\$58,004	\$48,871	\$31,620
Contract manufacturing product sales	\$8,995	\$17,033	\$11,877
Total product sales, net	\$66,999	\$65,904	\$43,497

The annual activity in the Company's allowance for customer deductions and doubtful accounts for the three years ended December 31, 2017, 2016 and 2015 is as follows (in thousands):

	Returns	Chargebacks & Rebates	Discounts	Doubtful Accounts	TOTAL
Balance at December 31, 2014	\$674	\$ 4,552	\$ 345	\$ 16	\$5,587
Provision	1,724	65,713	2,201	74	69,712
Charges processed	(1,464)	(57,815)	(1,754)	—	(61,033)
Balance at December 31, 2015	\$934	\$ 12,450	\$ 792	\$ 90	\$14,266
Provision	3,568	160,556	4,667	347	169,138
Charges processed	(2,192)	(137,125)	(2,156)	(20)	(141,493)
Balance at December 31, 2016	\$2,310	\$ 35,881	\$ 3,303	\$ 417	\$41,911
Provision	6,034	148,000	4,398	1,768	160,200
Charges processed	(7,023)	(159,809)	(6,737)	—	(173,569)
Balance at December 31, 2017	\$1,321	\$ 24,072	\$ 964	\$ 2,185	\$28,542

7. Goodwill and Intangible Assets

Goodwill

The Company acquired the assets of Canadian pharmaceutical company Alveda Pharmaceuticals, Inc., in November 2015. As a result of the acquisition, we recorded goodwill of \$0.4 million. We assess the recoverability of the carrying value of goodwill in the fourth quarter of each year, and whenever events occur or circumstances change that would, more likely than not, reduce the fair value of our reporting unit below its carrying value. There have been no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value. No impairment losses were recognized during the year ended December 31, 2017.

Changes in goodwill during the two years ended December 31, 2016 and December 31, 2017 were as follows (in thousands):

	Goodwill
December 31, 2015	\$ 426
Foreign currency translation	20
December 31, 2016	446
Foreign currency translation	25
December 31, 2017	\$ 471

Intangible Assets

The following sets forth the major categories of the Company's intangible assets and the weighted-average remaining amortization period as of December 31, 2017 and December 31, 2016 for those assets that are not already fully amortized (dollar amounts in thousands):

	December 31, 2017			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted Average Remaining Amortization Period
Trademarks and Technology	\$40,380	\$ (5,684)	\$ 34,696	12.8
In-process research and development ("IPR&D")	18,311	—	18,311	N/A - Indefinite lived
Customer relationships	3,783	(773)	3,010	7.9
Total	\$62,474	\$ (6,457)	\$ 56,017	
	December 31, 2016			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted Average Remaining Amortization Period
Trademarks and Technology	\$35,403	\$ (3,123)	\$ 32,280	13.8
In-process research and development ("IPR&D")	17,024	—	17,024	N/A - Indefinite lived
Customer relationships	3,565	(404)	3,161	8.9
Total	\$55,992	\$ (3,527)	\$ 52,465	

Changes in intangibles during the two years ended December 31, 2016 and December 31, 2017 were as follows (in thousands):

	Trademarks and Technology	IPR&D	Customer Relationships
December 31, 2015	\$ 36,552	\$ 14,351	\$ 3,417
Acquisition	661	2,811	—
Amortization	(2,472)	—	(361)
Foreign currency translation	(2,461)	(138)	105
December 31, 2016	32,280	17,024	3,161
Acquisition			
Amortization	(2,561)	—	(369)
IPR&D placed in service	834	(834)	—
Impairment	—	(113)	—
Foreign currency translation	4,143	2,234	218
December 31, 2017	\$ 34,696	\$ 18,311	\$ 3,010

Assuming no additions, disposals or adjustments are made to the carrying values and/or useful lives of the intangible assets, annual amortization expense on product rights and other related intangibles for each of the following years is estimated to be as follows (in thousands):

Year ending December 31,	Amortization Expense *
2018	2,930
2019	2,930
2020	2,930
2021	2,930
2022	2,930
Thereafter	23,058

*IPR&D amounts are assessed for impairment at least annually and will be amortized once products are approved, including the product's respective manufacturing process approvals, and are not included in the table.

The useful lives of the Company's intangibles is as follows:

Intangibles Category	Amortizable Life
Trademarks and Technology	15 years
Customer Relationships	10 years

8. Stock-Based Compensation

The 1999 Director Stock Option Plan, as amended (the "Director Plan"), provides for the grant of stock options to non-employee directors of the Company at an exercise price equal to the fair market value per share on the date of the grant. As of December 31, 2016, an aggregate of 1,975,000 shares had been approved and authorized for issuance pursuant to the Director Plan, with no change as of December 31, 2017. A total of 2,634,798 options had been granted to non-employee directors as of December 31, 2016, with no change as of December 31, 2017. A total of 807,782 of those options had been forfeited as of December 31, 2016 and returned to the option pool for future issuance, with no change as of December 31, 2017. The options granted under the Director Plan vest in full one year after their respective grant dates and have a maximum term of ten years. As of December 31, 2017 and December 31, 2016, there were 500,000 and 650,000 shares of common stock options outstanding, respectively. As of December 31, 2016, the 147,984 options available were transferred to a plan that has superseded the Director Plan, as discussed further in this section, with no additional options transferred as of December 31, 2017.

The 1999 Stock Incentive Plan, as amended (“1999 Plan”), replaced all previously authorized employee stock option plans, and no additional options may be granted under those previous plans. Under the 1999 Plan, options or stock awards may be granted to all of the Company’s employees, officers, directors, consultants and advisors to purchase a maximum of 3,200,000 shares of common stock. However, pursuant to the terms of the 1999 Plan, no awards may be granted after March 16, 2009. A total of 2,892,500 options, having a maximum term of ten years, have been granted at 100% of the fair market value of the Company’s

F-24

common stock at the date of grant. Options outstanding under the 1999 Plan are generally exercisable in cumulative increments over four years commencing one year from date of grant.

On June 26, 2009, the Board of Directors adopted, and the Company's stockholders subsequently approved by partial written consent, the IGI Laboratories, Inc. 2009 Equity Incentive Plan (the "2009 Plan"). The 2009 Plan became effective on July 29, 2009. The 2009 Plan allows the Company to continue to grant options and restricted stock, as under the 1999 Plan, but also authorizes the Board of Directors to grant a broad range of other equity-based awards, including stock appreciation rights, restricted stock units ("RSUs") and performance awards. The 2009 Plan has been created, pursuant to and consistent with the Company's current compensation philosophy, to assist the Company in attracting, retaining and rewarding designated employees, directors, consultants and other service providers of the Company and its subsidiaries and affiliates, in a manner that will be cost efficient to the Company from both an economic and financial accounting perspective. On April 12, 2010, the Board of Directors adopted, and the Company's stockholders subsequently approved, an amendment and restatement of the 2009 Plan to increase the number of shares of Common Stock available for grant under such plan by adding 2,000,000 shares of Common Stock. The 2009 Plan, as amended on May 29, 2010, authorizes up to 5,000,000 shares of the Company's common stock for issuance pursuant to the terms of the 2009 Plan. The maximum number of shares that may be subject to awards made to any individual in any single calendar year under the 2009 Plan is 1,000,000 shares. As of December 31, 2017, there were 99,626 RSUs outstanding, 1,422,020 shares of stock outstanding and 3,038,634 shares of common stock options outstanding. As of December 31, 2016, there were 179,900 RSUs outstanding, 1,341,746 shares of stock outstanding and 3,216,369 shares of common stock options outstanding. As of December 31, 2016, the 92,883 options available were transferred to a plan that has superseded the 2009 Plan, as discussed further in this section. As of December 31, 2017, an additional 156,169 options available were transferred to the superseded plan.

On May 25, 2016, the Board of Directors approved the Company's 2016 Equity Incentive Plan (the "2016 Plan"). The 2016 Plan provides for the issuance of awards of up to 2,000,000 shares of the Company's common stock, plus any shares of common stock that are represented by awards granted under our Director Plan and 2009 Plan that are forfeited, expire or are canceled without delivery of shares of common stock or which result in the forfeiture of shares of common stock back to the Company on or after May 25, 2016. Generally, shares of common stock reserved for awards under the 2016 Plan that lapse or are canceled, will be added back to the share reserve available for future awards. However, shares of common stock tendered in payment for an award or shares of common stock withheld for taxes will not be available again for grant. The 2016 Plan provides that no participant may receive awards for more than 1,000,000 shares of common stock in any fiscal year. As the 2016 Plan supersedes both the Director Plan and the 2009 Plan, any available shares from both are now incorporated into the 2016 Plan. As of December 31, 2017, there were 89,003 RSU's outstanding, 20,000 shares of common stock outstanding and options to purchase 761,176 shares of common stock outstanding under the 2016 Plan. As compared to 2017, as of December 31, 2016, there were 20,000 shares of common stock outstanding and options to purchase 239,000 shares of common stock outstanding under the 2016 Plan. As of December 31, 2017 and December 31, 2016, there were a total of 1,526,857 shares of common stock and 1,981,867 shares of common stock available under the 2016 Plan.

As of December 31, 2017 and December 31, 2016, there were options to purchase 4,299,810 shares of common stock and 4,105,369 shares of common stock outstanding, respectively, collectively in the Director Plan, 2009 Plan, and the 2016 Plan.

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 amendments had a de minimis value to the holders as of December 31, 2017,

and therefore no additional stock compensation expense was recognized. The forms of amendment are Exhibits 10.31 and 10.32, respectively, and are incorporated by reference herein.

Stock Options

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

F-25

Edgar Filing: Teligent, Inc. - Form 10-K

Assumptions	2017	2016	2015	
Expected dividends	0	% 0	% 0	%
Risk free rate	1.56	% 1.14	% 1.11	%
Expected volatility	58.0% - 69.7%	68.0% - 71.3%	52.7% - 68.3%	
Expected term (in years)	3.2 – 3.3 years	3.1 – 3.3 years	3.2 – 3.3 years	

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

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

	Shares	Exercise Price Per Share	Weighted Average Exercise Price
January 1, 2015 shares issuable under options	2,436,834	0.76 - 10.55	\$ 1.79
Granted	1,357,000	5.55 - 10.67	9.20
Exercised	(75,766)	0.76 - 3.62	1.10
Expired	—	—	—
Forfeited	(125,334)	1.40 – 10.67	8.99
December 31, 2015 shares issuable under options	3,592,734	0.79 - 10.67	4.36
Granted	739,135	4.72 - 8.81	7.26
Exercised	(61,834)	1.10 - 6.51	1.54
Expired	—	—	—
Forfeited	(164,666)	4.55 - 10.67	8.37
December 31, 2016 shares issuable under options	4,105,369	0.79 - 10.67	4.76
Granted	577,845	3.38 - 9.28	7.15
Exercised	(171,566)	0.79 - 5.85	1.92
Expired	—	—	—
Forfeited	(211,838)	4.80 - 10.67	7.70
December 31, 2017 shares issuable under options	4,299,810	\$0.79 - \$10.67	\$ 4.76

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2017:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number of Options	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
\$0.79 - \$1.00	25,000	2.01	\$ 0.79	25,000	\$ 0.79
1.01 - 1.50	1,721,000	4.14	1.06	1,721,000	1.06
1.51 - 10.67	2,553,810	7.76	7.85	1,369,466	7.92
\$0.79 - \$10.67	4,299,810	6.28	\$ 5.09	3,115,466	\$ 4.07

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2016:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number of Options	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
\$0.79 - \$1.00	50,000	3.01	\$ 0.79	50,000	\$ 0.79
1.01 - 1.50	1,808,400	5.11	1.07	1,808,400	1.07
1.51 - 10.67	2,246,969	8.35	7.82	805,803	7.15
\$0.79 - \$10.67	4,105,369	6.86	\$ 4.76	2,664,203	\$ 2.90

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2015:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number of Options	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
\$0.76 - \$1.00	50,000	4.01	\$ 0.79	50,000	\$ 0.79
1.01 - 1.50	1,862,400	6.14	1.07	1,851,400	1.07
1.51 - 10.55	1,680,334	8.96	8.10	289,997	4.02
\$0.79 - \$10.67	3,592,734	7.43	\$ 4.36	2,191,397	\$ 1.45

The Company has recorded an aggregate of \$2.3 million, \$2.3 million and \$1.7 million related to its stock option based expenses in cost of sales, product development and research expenses, and selling, general and administrative expenses on the accompanying Consolidated Statements of Operations for the years ended December 31, 2017, 2016 and 2015, respectively.

The aggregate intrinsic value of options outstanding was \$4.7 million at December 31, 2017, \$11.5 million at December 31, 2016 and \$17.4 million at December 31, 2015. The aggregate intrinsic value of the options exercisable was \$4.7 million at December 31, 2017, \$11.3 million at December 31, 2016 and \$16.3 million at December 31, 2015. The total intrinsic value of the options exercised during 2017, 2016 and 2015 was \$0.4 million, \$0.3 million and \$0.6 million, respectively.

A summary of non-vested options at December 31, 2017 and changes during the year ended December 31, 2017 is presented below:

	Options	Weighted Average Grant Date Fair Value
Non-vested options at January 1, 2017	1,441,166	\$ 3.58
Granted	577,845	3.37
Vested	(654,156)	3.62
Forfeited	(180,511)	3.46
Non-vested options at December 31, 2017	1,184,344	\$ 3.48

As of December 31, 2017, there was \$2.3 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements under the Plan. The costs will be recognized through December 2019.

Restricted Stock and RSUs

The Company periodically grants restricted stock and RSU awards to certain officers and other employees that typically vest one to three years from their grant date. On December 30, 2013, in accordance with the terms of the employment agreement between Jason Grenfell-Gardner, President and CEO, and the Company executed on July 30, 2012, a restricted stock award in the amount of 325,000 shares was granted to Jason Grenfell-Gardner, with one third of the shares of restricted stock vested on December 31, 2013, and the remaining two thirds of the shares of restricted stock vesting in equal amounts on July 30, 2014 and July 30, 2015. The Company recognized \$1 million, \$0.8 million and \$0.6 million, respectively, of compensation expense during the years ended

F-27

December 31, 2017, 2016 and 2015 related to restricted stock awards and RSUs. Stock compensation expense is recognized over the vesting period of the restricted stock and RSUs. At December 31, 2017, the Company had approximately \$0.7 million of total unrecognized compensation cost related to non-vested restricted stock and RSUs, all of which will be recognized through April 2020.

A summary of non-vested shares of restricted stock and changes during each of the past three years is as follows:

	Number of Restricted Stock	Weighted Average Issuance Price
Non-vested balance at January 1, 2015	108,334	\$ 2.86
Changes during the period:		
Shares granted	32,500	10.67
Shares vested	(140,834)	4.66
Shares forfeited	—	—
Non-vested balance at January 1, 2016	—	\$ —

There have been no restricted stock issuances in the year ended 2016 or 2017.

A summary of non-vested RSUs and changes during each of the past three years is as follows:

	Number of RSUs	Weighted Average Issuance Price
Non-vested balance at January 1, 2016	182,750	\$ 10.23
Changes during the period:		
Shares granted	58,068	7.50
Shares vested	(60,918)	10.13
Shares forfeited	—	—
Non-vested balance at December 31, 2016	179,900	\$ 9.35

Changes during the period:		
Shares granted	93,468	7.26
Shares vested	(80,274)	9.57
Shares forfeited	(4,465)	7.09
Non-vested balance at December 31, 2017	188,629	\$ 9.35

There was no RSU activity for the year ended December 31, 2015.

9. Accrued Expenses

Accrued expenses represent various obligations of the Company including certain operating expenses and taxes payable.

For the fiscal years ended December 31, 2017, and 2016 the largest components of accrued expenses were:

	2017	2016
	(in thousands)	
Wholesaler fees	\$7,044	\$3,505
Capital expenditures	1,947	2,475
Payroll	1,580	1,706
Royalties	856	843
Studies	596	153
Professional fees	546	715
Interest expense	240	240
Income Tax	58	192
Other	635	520
	\$13,502	\$10,349

10. Income Taxes

On December 22, 2017, the President signed into law the United States Tax Cuts and Jobs Act (U.S. TCJA) significantly revising the Internal Revenue Code of 1986, as amended. The U.S. TCJA includes, among other items, (1) a permanent reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; (2) limitations on the tax deduction for net interest expense to 30% of adjusted earnings' (3) a one-time transition tax on certain unrepatriated earnings of foreign subsidiaries; (4) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system; (5) elimination of the Alternative Minimum Tax regulations; (6) recovery of Alternative Minimum Tax Credits over a five year period; and (7) modifying or repealing many other business deductions and credits.

The Company has assessed the impacts of the changes resulting from the U.S. TCJA and has recognized an income tax benefit and a corresponding receivable of \$73 thousand related to the recoverability of Alternative Minimum Tax Credits. Deferred tax assets, liabilities and valuation allowances have been remeasured at the new rate of 21%. There was no income impact from the remeasurement since all U.S. net deferred tax assets are fully reserved by the Company. At present, we do not estimate any material impacts from the repatriation tax. While we have completed our provisional analysis of the income tax effects of the U.S. TCJA, the related tax effects may need to be adjusted, possibly materially, due to further refinement of our calculations, changes in interpretations and assumptions that we have made, additional guidance that may be issued by regulatory bodies, and actions and related accounting policy decision we may take as a result of the new legislation. We will complete our analysis over the one-year measurement period from the enactment of the law as provided for by SAB 118, and any adjustments during this measurement period will be included in net earnings from continuing operations as an adjustment to income tax expense in the reporting period(s) when such adjustments are determined.

The Company is subject to U.S. federal income tax and files a consolidated federal income tax return which includes all eligible U.S. subsidiary companies. The Company is also subject to tax in the states of Alabama, Illinois, Montana, New Jersey and Tennessee. During the year ended December 31, 2016, the Company began significant operations in certain foreign countries and is, accordingly, subject to tax in those foreign jurisdictions consisting of Canada (including the province of Ontario), Estonia, Luxembourg and Jersey.

Income (Loss) before income tax for the years ended December 31, 2017, 2016 and 2015 consisted of the following (in thousands):

2017	2016	2015
------	------	------

Edgar Filing: Teligent, Inc. - Form 10-K

(in thousands)

U.S. operations	\$(21,938)	\$(9,514)	\$6,911
Foreign operations	6,662	(2,184)	(208)
Global Total	\$(15,276)	\$(11,698)	\$6,703

F-29

Edgar Filing: Teligent, Inc. - Form 10-K

The Company's current tax (benefit) expense was \$(85,000), \$287,000 and \$35,000 for the years ended December 31, 2017, 2016 and 2015, respectively. The (credit) provision for income taxes attributable to continuing operations before income taxes for the years ended December 31, 2017, 2016 and 2015 is as follows (in thousands):

	2017	2016	2015
Current tax expense (benefit):			
Federal	\$(86)	\$26	\$—
State and local	20	35	19
Foreign	42	272	28
Total current tax expense	(24)	333	47
Deferred tax expense:			
Federal	—	—	—
State and local	—	—	—
Foreign	(61)	(46)	(12)
Total deferred tax expense	(61)	(46)	(12)
Total income tax (benefit)/expense	\$(85)	\$287	\$35

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

	2017	2016	2015
Expected Statutory expense (benefit)	\$(5,195)	\$(3,977)	\$2,244
U.S. TCJA recovery of alternative minimum tax credits	(73)	—	—
Change in the fair values of derivative and amortization of debt discount	2,939	2,584	(5,597)
Other non-deductible expenses	24	63	7
Change in valuation allowance including U.S. TCJA rate reduction	(2,012)	590	3,254
Reduction in deferred tax assets related to U.S. TCJA rate reduction	7,504	—	—
Shortfalls related to stock compensation expense	129	154	—
Tax rate differential - foreign vs. U.S.	(2,276)	822	114
State income taxes, net of federal benefit	13	23	13
Shortfalls related to stock compensation expense	129	154	—
Prior year true-up	(13)	—	—
Exchange gain	(13)	28	—
	\$(85)	\$287	\$35

Deferred tax balances included in the Consolidated Balance Sheets as of December 31, 2017 and 2016 consisted of the following:

Edgar Filing: Teligent, Inc. - Form 10-K

	2017	2016
	(in thousands)	
Deferred Tax Assets:		
Allowance for doubtful accounts	\$ 506	\$ 118
Inventory reserve	619	467
Accrued expenses	664	831
Property, plant and equipment	214	317
Tax operating loss carryforwards	9,327	10,962
Tax credit carryforwards	168	254
Stock compensation	1,817	2,301
Total deferred tax assets	13,315	15,250
Less valuation allowance	(13,309)	(15,250)
Net deferred tax assets	6	—
Deferred Tax Liabilities:		
Intangible assets	(165)	(205)
Total deferred tax liabilities	(165)	(205)
Net deferred tax liability	\$(159)	\$(205)

The Company evaluates the recoverability of its deferred tax assets based on its history of operating results, its expectations for the future, and the expiration dates of the net operating loss carry forwards. Based on the preponderance of the evidence, the Company has concluded that it is more likely than not that it will be unable to realize the net deferred tax assets in the immediate future and has established a full valuation allowance for substantially all deferred tax assets. Accordingly, the Company has provided a valuation allowance of \$13.3 million and \$15.3 million for the years ended December 31, 2017 and 2016, respectively, on its deferred tax assets. The change in the valuation allowance during the year 2017 was \$1.9 million, as follows:

Valuation allowance at beginning of year	\$ 15,250
Change in accounting for stock compensation windfalls	1,112
Current year operating loss	3,048
Change in tax rate to 21%	(7,504)
Other	1,403
Valuation allowance at end of year	\$ 13,309

Operating loss and tax credit carry forwards as of December 31, 2017 were as follows:

	2017	2016
	(in thousands)	
Federal:		
Net operating losses (expiring through 2037)	\$41,688	\$31,336
Research tax credits (expiring through 2025)	168	168
Alternative minimum tax credits (available without expiration)	—	86
State:		
Net Operating Losses:		
Tennessee (expiring in 2032)	659	529
New Jersey (expiring in 2037)	4,320	1,764
Illinois (expiring in 2037)	389	222
Alabama (expiring in 2032)	24	—
Foreign		
Net operating losses (no expiration)	\$255	\$232

At December 31, 2017, the Company's U.S. federal net operating loss carryforwards will expire as follows:

F-31

Year	Net Operating Loss (in thousands)
2020 - 2023	\$ 8,228
2024 - 2029	9,063
2030 - 2031	6,205
2032 - 2036	10,016
2037	8,176
Total	\$ 41,688

The Company's ability to use net operating loss carry forwards is subject to substantial limitation in future periods under certain provisions of Section 382 of the Internal Revenue Code of 1986, as amended, which limit the utilization of net operating losses upon a more than 50% change in ownership of the Company's stock that is held by 5% or greater stockholders. The Company examined the application of Section 382 with respect to an ownership change that took place during 2010, as well as the limitation on the application of net operating loss carry forwards. The Company believes that operating losses subsequent to the change date in 2010 (aggregating \$23.1 million) are not subject to Section 382 limitations. The Company has estimated that the annual limitation starting in 2010 aggregates from \$1.0 million to \$2.3 million per year including the effect of amortization of built in gains. The Company's loss carryforwards may be further limited in the future if additional ownership changes occur.

The Company is subject to the provisions of ASC 740-10-25, Income Taxes (ASC 740). ASC 740 prescribes a more likely-than-not threshold for the financial statement recognition of uncertain tax positions. ASC 740 clarifies the accounting for income taxes by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. On a quarterly basis, the Company undergoes a process to evaluate whether income tax accruals are in accordance with ASC 740 guidance on uncertain tax positions.

Federal income tax returns for the years 2014 and 2015 have been examined by the U.S. Internal Revenue Service without any income tax expense consequences. For federal purposes (except for the years 2014 and 2015), post 1998 tax years remain open to examination as a result of net operating loss carryforwards. The Company is currently open to audit by the appropriate state income taxing authorities for tax years 2013 through 2016. The Company has not recorded any liability for uncertain tax positions at December 31, 2017 or December 31, 2016.

11. Commitments

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

Commitments	
2018	\$ 491
2019	436
2020	441
2021	403
2022	327
2023	332
Thereafter ⁸³	
	\$ 2,513

Rent expense was \$0.5 million, \$0.9 million and \$0.4 million for the years ended December 31, 2017, 2016 and 2015, respectively.

The Company has certain licensing and development agreement in place under which the Company will pay certain licensing fees and milestones over the lives of certain projects. These commitments totaled approximately \$2.4 million as of December 31, 2017, and will be paid over the next several years in accordance with agreed upon milestones.

12. Legal and U.S. Regulatory Proceedings

F-32

On March 2, 2001, the Company became aware of environmental contamination resulting from an unknown heating oil leak at its former manufacturing facility. The Company immediately notified the New Jersey Department of Environmental Protection (“NJ DEP”) and the local authorities, and hired a contractor to assess the exposure and required clean up. The total estimated costs for the clean-up and remediation is \$889,000, of which approximately \$118,000 remains accrued as of December 31, 2017. 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 \$120,000 as of December 31, 2017 and \$122,000 as of December 31, 2016 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’s approval when the remediation is completed.

On December 19, 2013, the Company filed a complaint in the United States District Court for the District of Delaware against Mallinckrodt LLC, Mallinckrodt, Inc. and Nuvo Research Inc., 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 the Company 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 the Company infringed the patents at issue. On June 26, 2014, the Company entered into a settlement agreement with Mallinckrodt, pursuant to which Mallinckrodt granted us a non-exclusive license to launch the Company’s diclofenac sodium topical solution 1.5% product on March 28, 2015. There was no material impact on the Company’s financial statements as a result of the settlement. We received approval to sell the 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. (collectively, “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 (“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 and 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. (collectively, “Galderma”) filed a complaint in the United States District Court for the Northern District of Texas against the Company alleging infringement of United States Patent No. 6,106,848 based upon the Company’s 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.

To date, twelve putative class action antitrust lawsuits have been filed against Teligent Inc. along with co-defendants including Taro Pharmaceuticals U.S.A., Inc. and Perrigo New York Inc. One “opt-out” action has additionally been filed against the Company along with thirty-five generic manufacturer co-defendants regarding the pricing of econazole nitrate cream and twenty-nine additional drug products not manufactured or sold by the Company. All actions have been transferred by the Judicial Panel on Multidistrict Litigation to the Eastern District of Pennsylvania for pre-trial proceedings as part of the In re Generic Pharmaceuticals Pricing Antitrust Litigation matter, and the class actions have been consolidated into direct purchaser, end payer and indirect reseller actions.

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 until the time the defendants’ allegedly unlawful conduct ceased or will cease.

The case plaintiffs allege a conspiracy to fix prices for generic econazole, in violation of federal antitrust laws or state antitrust, consumer protection, and other laws. The case plaintiffs seek treble damages for alleged price overcharges for generic econazole during the alleged period of conspiracy, and the end payer and indirect purchaser class plaintiffs seek injunctive relief against the defendants.

The opt-out plaintiffs allege a conspiracy by thirty-six generic manufacturers, including the Company, to fix prices for thirty drug products including econazole nitrate cream, in violation of federal antitrust laws. The opt-out plaintiffs seek treble damages for alleged price overcharges for the thirty drug products identified in the complaint during the alleged period of conspiracy, and also seek injunctive relief against the defendants.

All of these cases are in their initial stages and motions to dismiss have been filed with respect to each of the complaints. 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 believe these cases are without merit, and we intend to vigorously defend against these claims.

On October 20, 2017, a Demand for Arbitration was filed with the American Arbitration Association by Stayma Consulting Services, Inc. (“Stayma”) against the Company regarding the Company’s development and manufacture for Stayma of two generic drug products, one a lotion and one a cream, containing 0.05% of the active pharmaceutical ingredient flurandrenolide. The Company developed the two products and Stayma purchased commercial quantities of each; however, Stayma now alleges that the Company breached agreements between the parties by developing an additional and different generic drug product, an ointment, containing flurandrenolide, and failing to meet certain contractual requirements. Stayma seeks monetary damages. Due to the early stage of this matter, 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 believe this case is without merit, and we intend to vigorously defend against these claims. We filed a counter-claim against Stayma for its failure to pay several past due invoices of approximately \$1.7 million relating to the development and commercial supply of the two subject products.

13. Employee Benefits

The Company has a 401(k) contribution plan, pursuant to which employees may elect to contribute to the plan, in whole percentages, up to 100% of compensation. Employees’ contributions are subject to a minimum contribution by participants of 1% of compensation and a maximum contribution of \$18,000 for 2017, \$18,000 for 2016 and \$18,000 for 2015, plus a catch-up contribution of up to \$6,000 for 2017, \$6,000 for 2016 and \$6,000 for 2015, if a participant qualifies. The Company matches 100% of the first 3% of compensation contributed by participants and 50% of the next 2% of compensation contributed by participants. The Company contribution is in the form of cash, which is vested immediately. The Company has recorded charges to expense related to this plan of approximately \$311,467, \$228,619 and \$172,965 in 2017, 2016 and 2015, respectively.

14. Quarterly Results (Unaudited)

The following is a summary of certain quarterly financial information for the fiscal years 2017 and 2016:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
	(in thousands, except per share data)				
Year Ended December 31, 2017					
Total revenues, net	\$ 19,891	\$ 18,408	\$ 12,851	\$ 16,101	\$ 67,251
Gross profit	10,934	8,037	2,538	5,863	27,372
Operating income (loss)	2,967	(1,782)	(8,039)	(4,943)	(11,797)
Net income (loss)	831	(919)	(8,982)	(6,121)	(15,191)
Net income (loss) attributable to common stockholders	831	(919)	(8,982)	(6,121)	(15,191)
Basic income (loss) per share	\$0.02	\$(0.02)	\$(0.17)	\$(0.11)	\$(0.28)
Diluted income (loss) per share	\$0.02	\$(0.02)	\$(0.17)	\$(0.11)	\$(0.28)
Year Ended December 31, 2016					
Total revenues, net	\$ 15,657	\$ 17,138	\$ 16,151	\$ 17,935	\$ 66,881
Gross profit	7,955	9,556	8,014	9,162	34,687
Operating income	837	1,076	303	326	2,542
Net loss	(950)	(2,901)	(2,703)	(5,431)	(11,985)
Net loss attributable to common stockholders	(950)	(2,901)	(2,703)	(5,431)	(11,985)
Basic loss per share	\$(0.02)	\$(0.05)	\$(0.05)	\$(0.11)	\$(0.23)
Diluted loss per share	\$(0.02)	\$(0.05)	\$(0.05)	\$(0.11)	\$(0.23)

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

	Balance at Beginning of Year	to Costs and Expenses	Additions Charged Charged other Accounts	Deductions	Balance at End of Year
Year Ended December 31, 2015					
Change in Tax Valuation Allowance	\$ 10,970	—	3,339	—	\$ 14,309
Allowance for Doubtful Accounts	\$ 16	74	—	—	\$ 90
Reserve for Inventory Obsolescence	\$ 212	51	(8) 134	\$ 121
Year Ended December 31, 2016					
Change in Tax Valuation Allowance	\$ 14,309	—	941	—	\$ 15,250
Allowance for Doubtful Accounts	\$ 90	347	—	20	\$ 417
Reserve for Inventory Obsolescence	\$ 121	872	—	583	\$ 410
Year Ended December 31, 2017					
Change in Tax Valuation Allowance	\$ 15,250	(61) (1,880) —	\$ 13,309
Allowance for Doubtful Accounts	\$ 417	1,768	—	—	\$ 2,185
Reserve for Inventory Obsolescence	\$ 410	2,000	9	1,115	\$ 1,304