Teligent, Inc.
Form 10-K
April 01, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended **December 31, 2018**
OR

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

For the transition period from _____ to _____

Commission file number: **001-08568**

Teligent, Inc.

(Formerly IGI Laboratories, Inc.)
(Exact name of registrant as specified in its charter)

Delaware	**01-0355758**
(State or other jurisdiction of incorporation	*(I.R.S. Employer Identification No.)*

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 ý

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

The aggregate market value of the registrant’s voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold, as of the last business day of the registrant’s most recently completed second fiscal quarter was $117.7 million.

As of March 25, 2019, the registrant had 53,845,427 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, 2019.

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 35 generic topical pharmaceutical products and four branded generic pharmaceutical products. In Canada, we sell over 27 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, Mississauga, 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 20 Abbreviated New Drug Applications ("ANDAs"), on file with the FDA, for additional pharmaceutical products. In addition, we have 3 submissions on file with Health Canada. We have an additional 46 product candidates at various stages of our development pipeline. We submitted three ANDAs in 2018. 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 twelve approvals from our internally developed pipeline of topical generic products in 2018. We intend to continue to submit further ANDAs to the FDA and abbreviated new drug submissions ("ANDS") to Health Canada in 2019. 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 10 employees and located in our offices in Mississauga, Canada. Teligent Canada acquired all of the Alveda working capital, including accounts receivable, inventory, accounts payable, and capital assets. In addition, Teligent Canada acquired Alveda's existing customer relations, all contracts necessary to execute the Canadian distribution activities, operational permits, and all intellectual property required to operate the marketing and distribution of products in Canada. Teligent Canada also transitioned a majority of the existing workforce as part of the acquisition. Teligent Canada currently markets and distributes over 27 products. Teligent continues to transition these products to distribute them under a Teligent Canada label.

Teligent OÜ. Teligent OÜ currently has 13 employees. 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 continued with the significant expansion and utilities upgrade of our manufacturing facility at 105 Lincoln Avenue in Buena, New Jersey. In October 2018, we received the Certificate of Occupancy to begin using 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 includes 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 greater than $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 successful FDA inspection, 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, for the 20 products we have pending at the FDA totals approximately $1.5 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 2019. We also have 46 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 ten employees, including a general manager located in our offices in Mississauga, 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 27 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, revenue from our contract services business may decrease over time.

Our Financings

On December 16, 2014, we issued $125.0 million aggregate principal amount of Convertible 3.75% Senior Notes, due 2019 (the "2019 Notes"). On December 22, 2014, we announced the closing of the initial purchasers' exercise in full of their option to purchase an additional $18.75 million aggregate principal amount of 2019 Notes. The 2019 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 2019 Notes are convertible into shares of our common stock, cash or a combination thereof. On May 20, 2015,we received shareholder approval for the increase in the number of shares of common stock authorized and available for issuance upon conversion of the 2019 Notes.

On April 27, 2018, we entered into separate exchange agreements with certain holders of the 2019 Notes. The agreements gave the holders the right to exchange, in aggregate, $75.1 million of the 2019 Notes for $75.1 million of new Convertible 4.75% Senior Notes due 2023 (the "2023 Notes"). The new 2023 Notes bear a fixed interest rate of 4.75% per year, payable semi-annually with the principal payable in May 2023. At the option of the holders, the 2023 Notes are convertible into shares of our common stock, cash or a combination thereof. The initial conversion rate is $224.71 per share, subject to certain adjustments, related to either our stock price volatility, or our declaration of a stock dividend, stock distribution, share combination or share split expected dividends or other anti-dilutive activities. In addition, holders will be entitled to receive additional shares of common stock for a potential increase of the conversion rate up to $280.90 per share under a make-whole provision in some circumstances. We incurred loan issue costs of $1.6 million upon issuance of the 2023 Notes. In accordance with accounting for convertible debt within the cash conversion guidance of ASC 470-20, we allocated the principal amount of the 2023 Notes between its liability and equity components. The carrying amount of the liability component was determined by measuring the fair value

of a similar debt instrument of similar credit quality and maturity that did not have the conversion feature. The carrying amount of the equity component, representing the embedded conversion option, was determined by deducting the fair value of the liability component from the principal amount of the 2023 Notes as a whole. The equity component was recorded to additional paid-in capital and is not remeasured as long as it continues to meet the conditions for equity classification. The excess of the principal amount of the 2023 Notes over the carrying amount of the liability component was recorded as a debt discount of $19.0 million, and is being amortized to interest expense using the effective interest method through the maturity date. We allocated the total amount of transaction costs incurred to the liability and equity components using the same proportions as the proceeds from the 2023 Notes. Transaction costs attributable to the liability component were recorded as a direct deduction from the liability component of the 2023 Notes, and are being amortized to interest expense using the effective interest method through the maturity date. Transaction costs attributable to the equity component were netted with the equity component of the 2023 Notes in additional paid-in capital. The effective interest rate of the 2023 Notes, inclusive of the debt discount and issuance costs, is 12.10%.

On June 1, 2018, we entered into a credit agreement for $25.0 million secured by all of our assets, due June 1, 2021 ("2021 Term Loan"). The 2021 Term Loan has limited financial and non-financial covenants inclusive of a minimum cash carry balance of $5.0 million. The 2019 Notes and 2023 Notes are subordinate to the 2021 Term Loan. The first $15.0 million of loan proceeds was received on June 1, 2018. The remaining loan proceeds of $10.0 million were subject to closing conditions as defined in the agreement and were received on July 16, 2018. The 2021 Term Loan incurred loan issue costs of $0.5 million and a discount of $0.4 million. The discount is due to lender fees paid on the initial drawdown of $15.0 million. The issue costs and discount are recognized as interest expense over the term of the 2021 Term Loan. The 2021 Term Loan bears interest at a rate of LIBOR plus 9%, with a stated floor of 2%. The effective interest, inclusive of the debt discounts and issue costs is 12.78% as of September 30, 2018. In December 2018 we used $25.6 million of proceeds from the Senior Credit Facilities (see below) to repay the 2021 Term Loan which was comprised of $25.0 million of principal, $0.5 million of transaction costs and $0.1 million of interest.. The repayment of the 2021 Term Loan is considered an debt extinguishment under ASC 470-50. We recorded $1.3 million of an extinguishment loss related to the repayment of the 2021 Term Loan in the Consolidated Statement of Operations.

On December 13, 2018, pursuant to a Commitment Letter, dated November 12, 2018, between us and Ares Management LLC, we entered into: (i) a First Lien Revolving Credit Agreement, by and among the Company, as the borrower, certain subsidiaries of the Company, as guarantors, the lenders from time to time party thereto, and ACF Finco I LP, as administrative agent (the "Revolver Credit Agreement") and (ii) a Second Lien Credit Agreement, by and among us, as the borrower, certain subsidiaries of ours, as guarantors, the lenders from time to time party thereto, and Ares Capital Corporation, as administrative agent (the "Second Lien Credit Agreement" and, together with the Revolver Credit Agreement, the "New Senior Credit Facilities").

The New Senior Credit Facilities consist of (i) a $25.0 million senior revolving credit facility governed by the Revolver Credit Agreement (the "New Revolver"); (ii) a $50.0 million second lien initial term loan (the "New Initial Term Loan"); (iii) a $30.0 million second lien delayed draw term loan A (the "Delayed Draw Term Loan A") and (iv) a $15.0 million second lien delayed draw term loan B (the "Delayed Draw Term Loan B" and, together with the Delayed Draw Term Loan A, the "Delayed Draw Term Loans" and, together with the New Initial Term Loan, the "New Term Loans"). The New Term Loans are governed by the Second Lien Credit Agreement. Our ability to borrow under the New Revolver is subject to a "borrowing base" to be determined based upon eligible inventory, eligible equipment, eligible real estate and eligible receivables. The Initial Term Loan of $50.0 million and $15.0 million of the Revolver were drawn by us on December 13, 2018. On December 21, 2018, we drew $20.0 million of the Delayed Draw Term Loan A. As of December 31, 2018 the $10.0 million of the Delayed Draw Term Loan A, $15.0 million of the Delayed Draw Term Loan B and $10.0 million of the Revolver remain available to the Company.

Use of Proceeds

The proceeds from the New Senior Credit Facility will be used for, among other things, the refinancing of certain of our outstanding indebtedness, including repayment of all borrowings under the Credit Agreement, dated as of June 1, 2018 for the 2021 Term Loan, among us, as the borrower, certain subsidiaries of ours, each as a guarantor, the lenders party thereto, and Cantor Fitzgerald Securities, as administrative agent (the "Existing Credit Agreement"), the repurchase or redemption of our outstanding 2019 Notes, as well as a construction project at our Buena, New Jersey facility, working capital, capital expenditures and other general corporate purposes, all as further set forth in the Revolver Credit Agreement and the Second Lien Credit Agreement.

Interest and Fees

The interest rate under the New Revolver is calculated, at the option of us, at either the one, two, three or six-month London Inter-Bank Offered Rate (or LIBOR) plus 3.75% or the base rate plus 2.75%. The interest rate on the New Term Loans is calculated, at the option of the Company at either LIBOR plus 8.75% or the base rate plus 7.75%.

Interest on the New Senior Credit Facilities is payable in cash except that interest on the New Term Loans is payable, at the option of us, in cash or in kind by being added to the principal balance thereof, until the earlier of December 13, 2020 and the date we have provided the lenders of the New Senior Credit Facilities financial statements demonstrating that we have attained twelve months of revenue of at least $125 million. A commitment fee of 1.0% per annum is payable by us quarterly in arrears on the unused portion of the Delayed Draw Term Loans.

Amortization and Prepayment

The New Senior Credit Facilities are not subject to amortization prior to maturity. Amounts drawn under the New Revolver may be prepaid at the option of us without premium or penalty, subject, in the case of acceleration of the New Revolver or termination of the revolving credit commitments thereunder, to certain call protections which vary depending on the time at which such prepayments are made. Amounts drawn under the New Revolver are subject to mandatory prepayment to the extent that aggregate extensions under the New Revolver exceed the lesser of the revolving credit commitment then in effect and the borrowing base then in effect, and upon the occurrence of certain events and conditions, including non-ordinary course asset dispositions, receipt of certain insurance proceeds and condemnation awards and issuances of certain debt obligations. Amounts

outstanding under the New Term Loans may be prepaid at the option of us subject to applicable premiums, including a make-whole premium, and certain call protections which vary depending on the time at which such prepayments are made. Subject to payment of outstanding obligations under the New Revolver as a result of any corresponding mandatory prepayment requirements thereunder, amounts outstanding under the New Term Loans are subject to mandatory prepayment upon the occurrence of certain events and conditions, including non-ordinary course asset dispositions, receipt of certain insurance proceeds and condemnation awards, issuances of certain debt obligations and a change of control transaction.

Guarantees and Collateral

The New Senior Credit Facilities were issued by the parent and guaranteed by subsidiaries, subject to certain exceptions. The New Revolver and related obligations are secured by a first priority security interest in and lien on substantially all of our assets and the assets of our subsidiary guarantors (the "Collateral"), subject to certain exceptions. The New Term Loans and related obligations are secured by a second priority security interest in the Collateral, subject to certain exceptions.

Covenants and Other Provisions

The New Senior Credit Facilities contain customary borrowing conditions, affirmative, negative and reporting covenants, representations and warranties, and events of default, including cross-defaults on other material indebtedness, as well as events of default triggered by a change of control and certain actions initiated by the FDA. In addition, effective March 31, 2019, we are required to comply at certain times with certain financial covenants consisting of a minimum revenue test, a minimum adjusted EBITDA test and a maximum total net leverage ratio. If an event of default occurs, the lenders of the New Revolver would be entitled to take enforcement actions, including foreclosure on Collateral and acceleration of amounts owed under the New Revolver, and the lenders under the New Term Loans would also be entitled to take such actions, subject to any limitations set forth in an intercreditor agreement with respect to the New Term Loans.

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

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 34 topical products under our own label. We have received FDA approvals for 34 topical generic products from our internally developed pipeline. In our topical pipeline, we have 20 ANDAs submitted to the FDA that are awaiting approval. We intend to continue to develop topical generic products and utilize our expertise in drug formulation and manufacture to expand our own generic topical prescription drug portfolio. We are targeting to develop and file further regulatory submissions with the FDA in 2019. 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 34 topical generic pharmaceutical products in our pipeline.

Injectable (I) - As part of the injectable phase of our TICO strategy, on September 24, 2014, we acquired from AstraZeneca previously approved ANDAs and NDAs associated with 18 products, 17 of which are injectable products and one of which is a non-injectable product for pain management. Of the products we acquired, two of the products are currently on the FDA drug shortage list. We have received FDA approval for our first product in this portfolio, Cefotan® (Cefotetan for Injection), which we launched in the first quarter of 2016.

On September 30, 2014, we acquired previously marketed and approved ANDAs associated with two ophthalmic products from Valeant, in addition to the exclusive right to acquire three additional previously marketed and approved injectable products from Valeant. In November 2014, we completed the purchase of 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 completed construction activities in the fourth quarter of 2018 and is intended to file for and receive FDA approval in 2019, 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 second quarter of 2017 for a generic version of an oral orphan drug and received a complete response letter from the FDA in the third quarter of 2018. The Company intends to respond to the FDA’s complete response letter in 2019. 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 27 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, 2018, and 2017, 54% and 52% 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, 2018, Cardinal accounted for 19% of our accounts receivable, ABC accounted for 19% of our accounts receivable, and McKesson accounted for 30% of our accounts receivable. As of December 31, 2017, Cardinal accounted for 44% of our accounts receivable, McKesson accounted for 15% of our accounts receivable, and ABC accounted for approximately 4% 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, 2018, approximately 79% of our contract services revenue was derived from pharmaceutical customers, as compared to 86% of total contract services revenue for the year ended December 31, 2017. None of our contract manufacturing services customers represented 10% of total revenue for the years ended December 31, 2018 and December 31, 2017.

Concentration of Risk. In 2018, we had sales to three customers which individually accounted for more than 10% of our total revenue. These customers had sales of $21.2 million, $7.3 million and $6.9 million, respectively, and represented 54% of total revenues in the aggregate. Accounts receivable related to these major customers comprised of 30%, 19% and 19%, respectively, and represented 68% of all accounts receivable as of December 31, 2018. In 2017, we had sales to three customers which individually accounted for more than 10% of our total revenue. These customers had sales of $17.0 million, $7.4 million and $6.9 million, respectively, and represented 52% of total

revenues in the aggregate. Accounts receivable related to these major customers comprised of 15%, 4% and 44%, respectively, and represented 63% 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 $12.3 million, $7.2 million and $6.8 million, respectively, and represented 41% of total revenues in the aggregate.

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, 2018, domestic net revenues were $45.6 million and foreign net revenues were $20.2 million. As of December 31, 2018, domestic net assets were $132.7 million and foreign assets were $58.2 million. For the year ended December 31, 2017, domestic net revenues were $47.0 million and foreign net revenues were $13.2 million. As of

December 31, 2017, domestic assets were $112.6 million and foreign assets were $72.0 million. For the year ended December 31, 2016, domestic net revenues were $52.8 million and foreign net revenues were $10.2 million.

Our Products

Lidocaine Ointment 5%, which we launched at the end of the first quarter of 2016, accounted for 7%, 17% and 23% of total revenues in 2018, 2017, and 2016, respectively. Zantac for injection, which the Company acquired in the fourth quarter of 2015, accounted for 5%, 10% and 3% of total revenues in 2018, 2017 and 2016, respectively.

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.

Teligent United States Topical Pharmaceutical Products

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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
Ciclopirox 1%	Shampoo	120mL	Loprox	Anti-fungal
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 0.05%	Cream	15g, 30g, 45g, 60g	Temovate Cream	Topical Corticosteroid
Clobetasol Propionate Emollient 0.05%	Cream	15g, 30g, 45g, 60g	TemovateE®	Topical Corticosteroid
Desoximetasone 0.25% (1)	Ointment	15g, 60g, 100g	Topicort®	Topical Corticosteroid
Desoximetasone 0.05%	Ointment	15g, 30g, 60g, 100g	Topicort®	Topical Corticosteroid
Diclofenac Sodium 1.5%	Topical Solution	150mL	Pennsaid®	Topical Anti-inflammatory
Diflorasone Diacetate 0.05%	Ointment	15g, 30g, 60g	PSORCON	Corticosteroid
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
Fluocinonide 0.05%	Gel	15g, 30g, 60g	Fluocinonide Gel	Topical Corticosteroid
Fluocinonide 0.05%	Ointment	15g, 30g, 60g	Lidex	Topical

				Corticosteroid
Fluocinonide 0.05%	Cream	15g, 30g, 60g, 120g	Fluocinonide Cream	Topical Corticosteroid
Flurandrenolide 0.05%	Ointment	15g, 30g, 60g	Cordran®	Topical Corticosteroid
Gentamicin Sulfate 0.1%	Ointment	15g, 30g	Gentamicin Ointment	Topical Anti-infective
Halobetasol Propionate 0.05%	Ointment	15g, 50g	Ultravate	Topical Corticosteroid
Hydrocortisone Butyrate 0.1%	Lotion	118mL, 59 mL	Locoid®	Topical Corticosteroid
Hydrocortisone 2.5%	Cream	30g, 1lb jar	Hydrocortisone Cream	Topical Steroid
Hydrocortisone 2.5%	Lotion	2oz	Hydrocortisone Lotion	Topical Steroid
Lidocaine 4%	Topical Solution	50mL	Xylocaine®	Topical Anesthetic
Lidocaine 5%	Ointment	35.44g	Xylocaine®	Topical Anesthetic
Lidocaine/Prilocaine 2.5% / 2.5%	Cream	5g, 30g	EMLA Cream	Local 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, 1lb 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 vial	Mucomyst®	ANDS	Antidote
Atropine	0.4 mg/mL, 0.6 mg/mL	Injectable	1 mL ampoule	N/A	DINA	Antimuscarnic, antispasmodic
Baclofen	0.05 mg/mL, 0.5mg/mL, 2mg/mL	Injectable	1mL, 5mL, 20mL ampoule	Lioresal®	ANDS	Muscle Relaxant
Ibuprofen for Intravenous Infusion	100 mg/mL	Injectable	8 mL vial	Caldolor®	NDS	Nonsteroidal Antiinflammatory Agent
Clindamycin Phosphate Topical Solution USP	1% w/v	Topical Solution	30 mL and 60 mL bottle	DalacinT®	ANDS	Topical Antibiotic
Cyanocobalamin	1000 mcg/mL	Injectable	1 mL ampoule, 10 mL vial	N/A	DINA	Hematopoietic
Diazepam	5 mg/mL	Injectable	2mL ampoule	Valium®	ANDS	Axiolytic - sedative
Diclofenac Sodium Solution	1.5% w/w	Topical Solution	150 mL, 60 mL bottle	Pennsaid®	ANDS	Topical Anti-inflammatory
Dimenhydrinate	50 mg/mL, 250 mg/mL	Injectable	1 mL ampoule, 5 mL vial	Gravol®	DINA	Antiemtic
Dobutamine	12.5 mg/mL	Injectable	20 mL vial	N/A	ANDS	Sympathomimetic
Epinephrine	1 mg/mL	Injectable	1 mL ampoule	Adrenalin®	DINA	Sympathomimetic
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 vial	Gemzar®	ANDS	Antineoplastic agent
Gentamicin	10 mg/mL, 40 mg/mL	Injectable	2mL ampoule	Garamycin®	ANDS	Antibiotic
Irinotecan Hydrochloride	20 mg/mL	Injectable	2 mL, 5 mL, 15 mL, 25 mL vial	Camptosar®	ANDS	Antineoplastic agent
Lidocaine 1%	10 mg/mL	Injectable	5 mL and 10 mL polyampoule, 5 mL glass	Xylocaine®	DINA	Local Anesthetic
Lidocaine 1% multidose	10 mg/mL	Injectable	20 mL and 50 mL vial	Xylocaine®	DINA	Local Anesthetic
Lidocaine 2%	20 mg/mL	Injectable	5 mL and 10 mL polyampoule	Xylocaine®	DINA	Local Anesthetic
Lidocaine 2% multidose	20 mg/mL	Injectable	20 mL and 50 mL vial	Xylocaine®	DINA	Local Anesthetic
Lidocaine 2% with epinephrine	20 mg/mL & 0.01 mg/mL	Injectable	20 mL and 50 mL vial	Xylocaine®	DINA	Local Anesthetic
Lidocaine Hydrochloride Topical Solution USP 4%	40 mg/mL	Topical Solution	50mL bottle	Xylocaine®	DINA	Topical Anesthetic

Lidocaine Ointment USP 5%	50 mg/g	Ointment	35g tube	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	Opitate Antagonist
Piperacillin and Tazobactam	2g/0.25 g, 3 g/0.375 g, 4 g/0.5 g	Injectable	2.25 g, 3.375 g, 4.5 g vial	Tazocin®	ANDS	Antibacterial for systemic use
Sodium Cloride	0.009	Injectable	10 mL polyampoule	N/A	DINA	Diluent
Sterile Water for Injection	1	Injectable	10 mL polyampoule	N/A	DINA	Diluent
Succinylcholine Chloride	20 mg/mL	Injectable	10 mL and 20 mL vial	Quelicin®	DINA	Muscle Relaxant
Sufentanil Citrate Injection	50 mcg/mL	Injectable	1 mL, 5 mL and 20 mL ampoule	N/A	ANDS	Opiate Anesthetic

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

Teligent United States Other Products

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

Product	**Strength**	**Formulation**	**Presentations**	**Brand equivalent**	**Dossier type held by Teligent**	**Therapeutic Classification**
Ciprofloxacin	0.3%	Ophthalmic Solution	2.5ml, 5ml, 10ml bottles	Ciloxan ®	ANDA	Antibacterial for systemic use
Betaxolol	0.5%	Ophthalmic Solution	5ml, 7.5ml, 15ml bottles	Betopic ®	ANDA	Beta Blocking Agent
Phytonadione	10mg, 1mg	Injectable	0.5ml, 1ml ampoules; 3cc, 6cc vials	AquaMephyton ®	NDA	Hemostatic
Amikacin Sulfate	50mg/ml, 250mg/ml	Injectable	2ml, 4ml vials	Amikacin Sulfate ®	ANDA	Antibacterial for systemic use
Calcitonin Salmon	200IU/ml	Injectable	2ml vials	Miacalcin ®	ANDA	Anti-parathyroid Agent
Cefotetan Disodium	20mg/ml	Injectable (bag)	50ml bags	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	10 mL ampules and 5 mL vials	N/A	NDA	Systemic multivitamin
Naloxone HCl	0.4 mg/mL, 1 mg/mL	Injectable	1 mL 5 mLand 10 mL vials	N/A	ANDA	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 mLand 35 mL vials	N/A	ANDA	Antibacterial for systemic use
Nalbuphine	10 mg/mL and 20 mg/mL	Injectable	1 mL and 10 mL vials	Nubain®	ANDA	Systemic analgesic

Our Suppliers

We require a supply of quality raw materials and components to manufacture and package pharmaceutical products for ourselves and third parties with which we have contracted. The principal components of our products are active and inactive pharmaceutical ingredients and certain packaging materials. The APIs and other materials and supplies used in our pharmaceutical manufacturing operations are generally available and purchased from many different U.S. and non-U.S. suppliers. However, in some cases, the raw materials used to manufacture pharmaceutical products are available only from a single supplier. Even when more than one supplier exists, we may choose, and in some cases have chosen, only to list one supplier in our applications submitted to the FDA. Any change in a supplier not previously approved must then be submitted through a formal approval process with the FDA.

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 is responsible for 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 incurred $14.1 million, $19.3 million, and $17.1 million in R&D expenses in 2018, 2017 and 2016, 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, 62% 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 38% 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 a 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. 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). 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.

Intellectual Property

To compete effectively, we need to develop and maintain a proprietary position with regard to our 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 which originally were 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 completed construction on an expansion of our Buena, New Jersey facility to total approximately 110,000 square feet. Although the injectable manufacturing lines installed have yet to receive FDA approval, we received a Certificate of Occupancy in the fourth quarter of 2018 and are currently occupying the space. Once FDA approved, 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. 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 lease additional warehouse space in Vineland, New Jersey, as needed to complement our existing warehouse capacity.

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 Mississauga, Canada and approximately 3,000 square feet of office and laboratory space in Tallinn, Estonia.

Employees

On December 31, 2018, we had a total of 189 full-time employees, including ten 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 1A. RISK FACTORS

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

Risks Related to Our Business

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

With the exception of 2015, our expenses exceeded our revenue in each of the last 13 years, and no net income has been available to common stockholders during each of these years. As of December 31, 2018, our stockholders' equity was $18.4 million and we had an accumulated deficit of $96.4 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 54% of our revenue for the year ended December 31, 2018, and three of our customers accounted for 52% of our revenue for the year ended December 31, 2017. 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 7% and 17% of our revenue for the years ended December 31, 2018 and 2017, 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 pressures of direct competition. For example, the competition we encounter may have a negative impact upon the prices we may charge for our products, the market share of our products and our revenue and profitability.

The pharmaceutical industry in which we operate is intensely competitive. The competition that we encounter has an effect on our product prices, market share, revenue and profitability. Depending upon how we respond to this competition, its effect may be materially adverse to us.

We compete with:

•the original manufacturers of the brand-name equivalents of our generic products; and

•other generic drug manufacturers.

Most of the products that we are developing are either generic drugs or products without patent protection. These drugs and 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, and it has recently finalized policies to implement the Competitive Generic Therapy ("GCT") designation pathway created by Congress in 2017 as part of FDARA. Based on these trends and regulatory developments, 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 the 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 by the FDA through a Prior Approval Supplement to each ANDA.

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 related to environmental protection and hazardous waste disposal. 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, 2018, and remaining costs accrued at December 31, 2018 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 the 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 U.S. Pharmacopeia, 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 Canadian 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.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may be subject to, or may in the future become subject to, U.S. federal and state, and foreign laws and regulations imposing obligations on how we collect, use, disclose, store and process personal information. Our actual or perceived failure to comply with such obligations could result in liability or reputational harm and could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In many activities, including the conduct of clinical trials, we are subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. We must comply with laws and regulations associated with the international transfer of personal data based on the location in which the personal data originates and the location in which it is processed. Although there are legal mechanisms to facilitate the transfer of personal data from the European Economic Area, or EEA, and Switzerland to the United States, the decision of the European Court of Justice that invalidated the safe harbor framework has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it was no longer possible to rely on safe harbor certification as a legal basis for the transfer of personal data from the European Union to entities in the United States. In February 2016, the European Commission announced an agreement with the Department of Commerce, or DOC, to replace the invalidated safe harbor framework with a new EU-U.S. “Privacy Shield.” On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its recent ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and Federal Trade Commission and making commitments on the part of public authorities regarding access to information.

The privacy and security of personally identifiable information stored, maintained, received or transmitted, including electronically, subject to significant regulation in the United States and abroad. While we strive to comply with all applicable privacy and security laws and regulations, legal standards for privacy continue to evolve and any failure or perceived failure to comply may result in proceedings.

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. The U.S. Department of Health and Human Services ("DHHS") has issued a proposed rule that would remove safe harbor protections for certain rebates, which if finalized as released would go into effect in January 2020. Given the complexity of the drug pricing systems in the United States, DHHS is also soliciting input on multiple issues and other proposals as part of this formal rulemaking process, and the timeline for any final government action could be lengthy. It is unclear what changes a DHHS final rule, if any, would make to the current drug rebate rules for Medicare and Medicaid programs, and what the potential impact of such changes would be to our business or 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 a "covered recipient," which include physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and beginning in 2022, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives following an expansion of the law by Congress in 2018. Applicable manufacturers and group purchasing organizations also must report annually ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other "transfers of value" to such physician owners and their immediate family members;

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

•the Foreign Corrupt Practices Act, or 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.

There also continues to be uncertainty that any provisions of the Affordable Care Act will continue to exist in their current form. Certain legislators are continuing their efforts to repeal the Act, although there is little clarity on how such a repeal would be implemented and what an Affordable Care Act replacement might look like, and there continue to be lawsuits in federal courts seeking to invalidate parts or all of the Act. For the immediate future, there continues to be significant uncertainty regarding the health care, health care coverage and health care insurance markets. The 116th Congress convened in January 2019 is expected to focus on health care markets broadly and also to target widely publicized cases of product failures as well as corporate misconduct in the health care industry writ large. The 116th Congress has a much different House of Representatives than the prior 115th Congress, and these and other political changes create additional uncertainty for all industries offering goods and services to medical professionals, including generic pharmaceuticals like ours.

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, 2018 the value of our goodwill and intangible assets net of accumulated amortization was $48.8 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 such factor 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 the FDA. Enforcement actions and litigation may result in verdicts against us, which may include significant monetary awards, judgments that certain of our intellectual property rights are invalid or unenforceable and injunctions preventing the manufacture, marketing and sale of our products. If disputes are resolved unfavorably, our business, financial condition and results of operations may be adversely affected.

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

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

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

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

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

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

After the FDA or Health Canada approves a drug for marketing under an NDA, ANDA, NDS, or ANDS, the product's sponsor must comply with several post-marketing obligations that continue until the product is discontinued. These post-marking obligations include the prompt reporting of serious adverse events to the appropriate regulatory agency or agencies, 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, 2018. We identified a number of material weaknesses in our internal control over financial reporting and concluded that, as of December 31, 2018, 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. In addition, on March 15, 2018, we filed an amendment to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 and on December 12, 2018, we filed an amendment to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, in each case in order to revise and restate certain items disclosed in such reports. 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 2019 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, if additional material weaknesses are found in our internal controls in the future, or if our external auditors cannot attest to the effectiveness of our internal control over financial review 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, 2018, we had federal net operating loss carry forwards, or NOLs, of approximately $45.1 million which expire from 2020 through 2037. Federal operating losses arising during and after 2018 are not subject to expiration; however, their usage is limited to 80% of taxable income during the year of use. 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 $26.5 million) are not subject to Section 382 limitations. We have estimated that the annual limitation starting in 2010 aggregates from $1.0 million to $2.3 million per year including the effect of amortization of built in gains.

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 2014 through 2017.

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 “United States Tax Cuts and Jobs Act,” or U.S. TCJA, significantly revising the Internal Revenue Code of 1986, as amended, or the Code. The U.S. 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. We urge investors to consult with their legal and tax advisers regarding the implications of the U.S. TCJA on an investment in our common stock.

We are currently involved in antitrust litigation related to our pricing practices. which is also part of a larger investigation by the attorneys general of forty-five states into alleged generic drug price fixing schemes and asserting claims under federal antitrust law (specifically, section 1 of the Sherman Act).

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.

We may be subject to, or may in the future become subject to, U.S. federal and state, and foreign laws and regulations imposing obligations on how we collect, use, disclose, store and process personal information. Our actual or perceived failure to comply with such obligations could result in liability or reputational harm and could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In many activities, including the conduct of clinical trials, we are subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. We must comply with laws and regulations associated with the international transfer of personal data based on the location in which the personal data originates and the location in which it is processed. Although there are legal mechanisms to facilitate the transfer of personal data from the European Economic Area, or EEA, and Switzerland to the United States, the decision of the European Court of Justice that invalidated the safe harbor framework has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it was no longer possible to rely on safe harbor certification as a legal basis for the transfer of personal data from the European Union to entities in the United States. In February 2016, the European Commission announced an agreement with the Department of Commerce, or DOC, to replace the invalidated safe harbor framework with a new EU-U.S. “Privacy Shield.” On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its recent ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and Federal Trade Commission and making commitments on the part of public authorities regarding access to information.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further in our operations as a public company, future government shutdowns could

impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our 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, 2018, the average daily trading volume of our common stock on the Nasdaq Global Select Market was approximately 518,868 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. We did not timely file our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, which quarterly report was filed on December 12, 2018. 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, 2018, and our management concluded that our disclosure controls and procedures were not effective as of December 31, 2018, solely because of the material weaknesses 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 $1.13 in the fourth quarter of 2018 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;

•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. On November 13, 2018, we received a notification letter from The Nasdaq Stock Market advising that, because we did not timely file our Quarterly Report on Form 10-Q for the period ended September 30, 2018, we were not in compliance with Listing Rule 5250(c)(1), which requires timely filing of all required periodic financial reports with the SEC. While we regained compliance with Listing Rule 5250(c)(1) on December 12, 2018, if in the future we fail to meet this or any other continued listing standard 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 our Notes and Credit Facilities

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 2019 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. On May 1, 2018, we entered into separate, privately negotiated exchange agreements with certain holders of the Notes to exchange an aggregate principal amount of approximately $75 million of the 2019 Notes in exchange for an equal amount of our 4.75% Convertible Senior Notes due 2023, or the 2023 Notes (together with the 2019 Notes, the "Notes"). Pursuant to the terms of the indentures 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 indentures), 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.

As of December 31, 2018, our total consolidated indebtedness was $175.8 million. Our substantial level of indebtedness coupled with our net loss 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 and New Senior Credit Facilities, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

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

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

Our ability to make scheduled payments and satisfy our other obligations pursuant to our Senior Credit Facility depends on our future operating performance and on economic, financial, competitive, and other factors beyond our control.

On December 13, 2018, pursuant to a previously disclosed commitment letter by and between us and Ares Management LLC, we entered into: (i) a First Lien Revolving Credit Agreement, by and among us, as the borrower, certain subsidiaries of ours, as guarantors, the lenders from time to time party thereto, and ACF Finco I LP, as administrative agent (the "Revolver Credit Agreement") and (ii) a Second Lien Credit Agreement, by and among us, as the borrower, certain subsidiaries of ours, as guarantors, the lenders from time to time party thereto, and Ares Capital Corporation, as administrative agent (the "Second Lien Credit Agreement" and, together with the Revolver Credit Agreement, the "Senior Credit Facilities"). The Senior Credit Facilities consist of a $25.0 million senior revolving credit facility governed by a Revolver Credit Agreement, a $50.0 million second lien initial term, a $30.0 million second lien delayed draw term loan A and a $15.0 million second lien delayed draw term loan B. The interest rate under the revolver is calculated at either the one, two, three or six-month London Inter-Bank Offered Rate, or LIBOR plus 3.75%, or the base rate plus 2.75%. The interest rate on the new term loans is calculated at either LIBOR plus 8.75% or the base rate plus 7.75%.

We may not generate sufficient cash flow from operations to cover required interest and principal payments, which could result in an event of default and acceleration of our obligations under these agreements, which may require us to seek additional financing or restructure existing debt on unfavorable terms. In addition, adverse changes in credit markets could increase our cost of borrowing and make it more difficult for us to obtain financing.

Restrictive covenants in our Senior Credit Facilities may interfere with our ability to obtain additional advances under existing credit facilities or to obtain new financing or to engage in other business activities.

Our Senior Credit Facilities contain certain affirmative, negative, and financial covenants, including cross-defaults on other material indebtedness, as well as events of default triggered by a change of control and certain actions initiated by the FDA. In addition, we are required to comply with certain financial covenants consisting of a minimum revenue test, a minimum adjusted EBITDA test and a maximum total net leverage ratio.

These restrictions may interfere with our ability to obtain additional advances under our credit facilities or to obtain restrictions may interfere with our ability to obtain additional advances under existing credit facilities or to obtain new financing or to engage in other business activities, which may inhibit our ability to grow our business and increase revenue. In addition, If an event of default occurs, the lenders of the revolver would be entitled to take enforcement actions, including foreclosure on collateral and acceleration of amounts owed under the revolver, and the lenders under the new term loans would also be entitled to take such actions, subject to any limitations set forth in an inter creditor agreement with respect to the new term loans, which in each case could have a material adverse effect on our business, financial condition and results of operations.

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 and the Senior Credit Facilities.

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, to pay the principal of and interest on our Senior Credit Facilities, and our creditworthiness generally.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

The Company's executive administrative offices are located in Buena, New Jersey, in two facilities now totaling approximately 110,000 square feet with the expansion of the facility completed in the fourth quarter of 2018 is 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 additional square feet of warehouse space as needed 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 Mississauga, Canada. The Company also leases approximately 3,000 square feet of office and laboratory space in Tallinn, Estonia.

Item 3. LEGAL PROCEEDINGS

To date, twelve putative class action antitrust lawsuits have been filed against the Company along with co-defendants, including Taro Pharmaceuticals U.S.A., Inc. and Perrigo New York Inc., regarding the pricing of generic econazole nitrate cream ("econazole"). The class plaintiffs seek to represent nationwide or state classes consisting of persons who directly purchased, indirectly purchased, paid and/or reimbursed patients for the purchase of generic econazole from July 1, 2014 until the time the defendants' allegedly unlawful conduct ceased or will cease. The class plaintiffs seek treble damages for alleged overcharges for econazole during the alleged period of conspiracy, and certain of the class plaintiffs also seek injunctive relief against the defendants. All actions have been consolidated 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. On October 16, 2018 the court dismissed the class plaintiffs' claims against the Company with leave to replead. On December 21, 2018 the class plaintiffs filed amended complaints, which the Company moved to dismiss on February 21, 2019. This motion remains pending.

Three "opt-out" antitrust lawsuits have additionally been filed against the Company by Humana Inc.; The Kroger Co. et al.; and United HealthCare Services, Inc., and consolidated into the In re Generic Pharmaceuticals Pricing Antitrust Litigation matter by the Judicial Panel on Multidistrict Litigation. Each of the opt-out complaints names between thirty-six and forty-three defendants (including the Company) and involves allegations regarding the pricing of econazole along with between twenty-four and twenty-nine other drug products that were not manufactured or sold by the Company during the period at issue. The opt-out plaintiffs seek treble damages for alleged overcharges for the drug products identified in the complaint during the alleged period of conspiracy, and two of the complaints also seek injunctive relief. A motion to dismiss the Humana Inc. and The Kroger Co., et al. opt-out complaints was filed on February 21, 2019. A motion to dismiss the United HealthCare Services, Inc. opt-out complaint has not yet been filed.

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 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. Because discovery in this matter is ongoing, the Company is 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. The Company believes this case is without merit, and the Company intends to vigorously defend against these claims. The Company filed three counter-claims 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 and for breaching the confidentiality provisions and exclusivity provisions of the parties' agreements.

On December 13, 2018, Valdepharm SA filed a lawsuit alleging that the Company breached contracts regarding two drug products that the Company had sought to have Valdepharm manufacture. On February 12, 2019 the Company answered the complaint and counterclaimed, alleging that Valdepharm breached the contracts by failing to perform its work in compliance with FDA regulations and current Good Manufacturing Practices. Each party seeks damages associated with the alleged breach and related claims. Due to the early stage of the case 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 the claims against Teligent are without merit, and we intend to vigorously defend against them.

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.

Stockholders

As of March 25, 2019, there were approximately 345 stockholders of record of our 53,845,427 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.

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. SELECTED FINANCIAL DATA

As discussed in Note 1, *Correction of Previously Issued Consolidated Financial Statements,* in the Company's consolidated financial statements included in Item 8, the consolidated financial statements of the Company for years ended December 31, 2017 and 2016 have been revised to give effect to the correction of certain immaterial accounting errors described therein. Accordingly, the 2017 and 2016 selected consolidated financial data presented in the table below has been revised to give effect to the correction of these immaterial accounting errors, as derived from the Company's audited consolidated financial statements included in Item 8. In addition, the immaterial accounting errors discussed in Note 1 originated prior to fiscal year 2016 and as such, the 2015 and 2014 selected consolidated financial data presented in the table below has also been revised to give effect to the correction of these immaterial accounting errors. The revised selected consolidated financial data presented below should be read in conjunction with the Company's consolidated financial statements included in Item 8 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,				
	2018	**2017**	**2016**	**2015**	**2014**
(In thousands, except per share data)					
Revenues	$ 65,865	$ 60,202	$ 63,012	$ 37,940	$ 30,647
Gross profit	22,385	27,372	34,687	21,315	16,972
Operating (loss) income	(15,099)	(11,797)	2,542	(3,192)	3,906
Interest and other non-operating income (expense)	(21,219)	(3,479)	(14,240)	9,895	1,518
Foreign currency exchange (loss) gain	(3,371)	7,719	(936)	109	—
Loss before income tax expense	(36,318)	(15,276)	(11,698)	6,703	5,424
Income tax (benefit) provision	(62)	(85)	287	35	173
Net (loss) income	(36,256)	(15,191)	(11,985)	6,668	5,251
Net (loss) income attributable to common stockholders	(36,256)	(15,191)	(11,985)	6,668	5,251
Weighted average shares outstanding:					

Basic	53,593	53,324	53,078	52,873	49,818
Diluted	53,593	53,324	53,078	67,112	64,207
PER SHARE:					
Net (loss) income:					
Basic	(0.68)	(0.28)	(0.23)	0.13	0.11
Diluted	(0.68)	(0.28)	(0.23)	(0.07)	0.09
BALANCE SHEET DATA:					
Current assets	$ 48,386	$ 59,131	$ 101,965	$ 115,542	$ 176,743
Property, plant and equipment, net	91,775	68,355	26,215	8,706	3,262
Total assets	190,892	184,585	181,895	183,503	196,603
Current liabilities	32,612	18,696	13,632	9,509	12,527
Long-term obligations, less current installments	139,859	121,136	111,596	107,235	144,942
Stockholders' equity	18,421	44,753	56,667	66,759	39,134
CASH FLOW DATA:					
Net cash (used in) provided by operating activities	$ (13,275)	$ 398	$ (447)	$ (15,459)	$ (3,767)
Net cash used in investing activities	(25,294)	(40,429)	(20,076)	(53,068)	(3,792)
Net cash provided by (used in) financing activities	25,333	269	(10)	(3,111)	164,465
Net (decrease)/increase in cash, cash equivalents and restricted cash	(13,236)	(39,762)	(20,533)	(71,638)	156,906

Revenues for the years ended December 31, 2015 and 2014 have been adjusted by $6.3 million and $3.1 million respectively. Current assets, Total assets and Current liabilities as of December 31, 2015 have been adjusted by $1.3 million respectively and Current assets, Total assets and Current

liabilities as of December 31, 2014 have been adjusted by $0.5 million respectively to correct for the immaterial errors described in footnote 1 to the consolidated financial statements.

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.

As discussed in Note 1, *Correction of Previously Issued Consolidated Financial Statements*, in the Company's consolidated financial statements included in Item 8, the Company's consolidated financial statements for years ended December 31, 2017 and 2016 have been revised to give effect to the correction of certain immaterial accounting errors described therein. Accordingly, the discussion and analysis presented below for the years ended December 31, 2017 and 2016 has also been revised to give effect to the correction of these immaterial accounting errors. The revised discussion and analysis presented below provides information to assist in understanding the Company's financial condition and results of operations and, as such, should be read in conjunction with the Company's consolidated financial statements included in Item 8.

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 35 generic topical pharmaceutical products and four branded generic pharmaceutical products. In Canada we sell a total of over 27 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, Mississauga, 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 20 Abbreviated New Drug Applications ("ANDAs") for additional pharmaceutical products filed with the FDA. We have six abbreviated new drug submissions ("ANDSs") on file with Health Canada. In addition, we have 46

product candidates at various stages of our development pipeline. We expect to continue to expand our presence in the generic pharmaceutical market through the filing of additional ANDAs with the FDA, the filing of applications to Health Canada and the subsequent launch of products as these applications are approved. 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 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.

Product and Pipeline Approvals

The following is a summary of approvals received in 2018:

On February 14, 2018, we announced approval of an ANDA for Betamethasone Dipropionate Lotion USP (Augmented), 0.05%. This was our first approval for 2018 and our twentieth approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We launched this product in May of 2018.

On March 21, 2018, we announced approval of an ANDA for Halobetasol Propionate Ointment, 0.05%. This was our second approval for 2018 and our twenty-first approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We launched this product in April of 2018.

On April 6, 2018, we announced approval of an ANDA for Ciclopirox Shampoo, 1%. This was our third approval for 2018 and our twenty-second approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We launched this product in May of 2018.

On April 17, 2018, we announced approval of an ANDA for Clobetasol Propionate Cream USP, 0.05%. This was our fourth approval for 2018 and our twenty-third approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We launched this product in May of 2018.

On June 13, 2018, we announced approval of an ANDA for Diflorasone Diacetate Ointment, 0.05%. This was our fifth approval for 2018 and our twenty-fourth approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We launched this product in August of 2018.

On June 20, 2018, we announced approval of an ANDA for Fluocinonide Gel USP, 0.05%. This was our sixth approval for 2018 and our twenty-fifth approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We launched this product in October 2018.

On July 2, 2018, we announced approval of an ANDA for Lidocaine and Prilocaine Cream USP, 2.5%/2.5%. This was our seventh approval for 2018 and our twenty-sixth approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We launched this product in November of 2018.

On July 24, 2018, we announced approval of an ANDA for Hydrocortisone Cream USP, 2.5%. This was our eighth approval for 2018 and our twenty-seventh approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We expect to launch this product in the third quarter of 2019.

On July 30, 2018, we announced approval of an ANDA for Hydrocortisone Lotion USP, 2.5%. This was our ninth approval for 2018 and our twenty-eighth approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We expect to launch this product in the second quarter of 2019.

On October 2, 2018, we announced approval of an ANDA for Fluocinonide Ointment USP, 0.05%. This was our tenth approval for 2018 and our twenty-ninth approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We launched this product in November of 2018.

On October 17, 2018, we announced approval of an ANDA for Fluocinonide Cream USP, 0.05%. This was our eleventh approval for 2018 and our thirtieth approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We expect to launch this product in the fourth quarter of 2019.

On October 24, 2018, we announced approval of an ANDA for Desoximetasone Ointment USP, 0.05%. This was our twelfth approval for 2018 and our thirty-first approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We expect to launch this product in the first quarter of 2019.

Results of Operations

Fiscal Year ended December 31, 2018 compared to year ended December 31, 2017

We had a net loss of $36.3 million, or $0.68 per share, during the year ended December 31, 2018 ("Current Year") compared to net loss of $15.2 million, or $0.28 per share, during the year ended December 31, 2017 ("Prior Year"). Product Sales, net, include Company Product Sales and Contract Manufacturing Sales, as follows:

Revenues (in thousands):

	Year Ended December 31,		Increase/(Decrease)	
Components of Revenue:	**2018**	**2017**	**$**	**%**
Product sales, net	$ 65,638	$ 59,950	$ 5,688	9%
Research and development services and other income	227	252	(25)	(10)%
Total Revenues	$ 65,865	$ 60,202	$ 5,663	9%

Total revenues increased 9%, or $5.7 million, to $65.9 million Current Year from $60.2 million Prior Year. The increase was primarily due to (i) increased revenue from the expansion of our own generic pharmaceutical product line of $1.6 million, (ii) increased revenues from our specialty generic injectable portfolio in Canada of $7.0 million, partially offset by (iii) decreased contract manufacturing revenues of $3.0 million.

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

Costs and expenses (in thousands):

	Year Ended December 31,		Increase/(Decrease)	
	2018	**2017**	**$**	**%**
Cost of revenues	$ 43,480	$ 32,830	$ 10,650	32%
Selling, general and administrative	23,408	19,904	3,504	18%
Product development and research	14,076	19,265	(5,189)	(27)%
Totals costs and expenditures	$ 80,964	$ 71,999	$ 8,965	12%

Total costs and expenditures increased 12%, or $9.0 million to $81.0 million in the Current Year from $72.0 million in the Prior Year. Cost of revenues increased as a percentage of total revenue to 66% in the Current Year as compared to 55% in the Prior Year. Cost of revenues increased $10.7 million in the Current Year mainly due to $8.2 million increase from incremental sales volume and $1.9 million increase from incremental material price. Our rapid growth has contributed to some production inefficiencies, as we have expanded our manufacturing footprint and capacity in topical manufacturing and have added sterile manufacturing capabilities to our facility. Cost of revenues included an incremental change in inventory reserves of $1.5 million related to inventory and raw materials that were expected to expire in less than six months.

Selling, general and administrative expenses in the Current Year increased by $3.5 million as compared to the Prior Year. The changes primarily consist of (i) $1.9 million impairment loss in the Current Year as compared to $0.1 million from the Prior year, (ii) $2.5 million incremental professional fees in the Current Year including ongoing legal litigation, and audit fees, partially offset by (iii) a reduction of $1.2 million in bad debt related expenses in the Current Year.

Product development and research expenses decreased by $5.2 million as compared to the Prior Year. As we shift focus from our portfolio of topical generic prescription pharmaceutical products to injectable generic pharmaceutical products with the addition of our new facility, we saw a lower investment in R&D for 2018. This was mainly due to (i) $4.1 million decrease in clinical studies, (ii) $0.7 million decrease in salaries and related costs inclusive of stock based compensation related to options

and restricted stock, (iii) $1.3 million decrease in exhibit and pilot batch costs, partially offset by (iv) $0.6 million increase to overhead costs related to the R&D department as we expand in order to utilize our new facilities and injectable pipeline of products and $0.3 million increase in GDUFA and associated fees.

Other (Expense) Income, net (in thousands):

	Year Ended December 31,		Increase/(Decrease)	
	2018	2017	$	%
Interest and other expense, net	$ (12,298)	$ (11,198)	$ 1,100	10%
Foreign exchange (loss) / gain	$ (3,371)	$ 7,719	$ 11,090	144%
Debt partial extinguishment of 2019 Notes	$ (4,235)	$ —	$ 4,235	100%
Debt extinguishment of 2021 term loan	$ (1,315)	$ —	$ 1,315	100%

Other (Expense) income, net increased in the Current Year primarily as a result of a $4.2 million loss on debt extinguishment from the 2019 Notes and $1.3 million from the loss on debt extinguishment from the 2021 Term Loan in addition to $1.5 million of interest expense from the 2021 Term loan and $0.5 million of interest expense from the Ares financings partially offset by an increase in capitalized interest of $0.8 million.

Foreign exchange loss of $3.4 million in the Current Year is related to the foreign currency translation of our intercompany loans denominated in U.S. dollars to our foreign subsidiaries 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 remaining term of these loans.

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

	Year Ended December 31,		Increase/(Decrease)	
	2018	2017	$	%
Net loss attributable to common stockholders	$ (36,256)	$ (15,191)	$ 21,065	(139%)
Basic and diluted loss per share	$ (0.68)	$ (0.28)	$ 0.40	(143%)

Net loss for the Current Year was $36.3 million as compared to net loss of $15.2 million for the Prior Year. The increase is primarily due to increase i) in costs and expenses of $9.0 million, ii) in interest and other expenses of $1.1

million, iii) in foreign exchange loss of $11.1 million, (iv) debt extinguishment losses of $5.5 million, partially offset by an increase in revenues of $5.7 million in the Current Year as discussed above.

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):

	Year Ended December 31,		Increase/(Decrease)	
Components of Revenue:	**2017**	**2016**	**$**	**%**
Product sales, net	$ 59,950	$ 62,035	$ (2,085)	(3%)
Research and development services and other income	252	977	(725)	(74%)
Total Revenues	$ 60,202	$ 63,012	$ (2,810)	(4%)

The decrease in product sales for the year ended December 31, 2017 as compared to the same period in 2016 was primarily due to a decrease in contract manufacturing revenues of $8.0 million, specifically related to a decline in sales to one of our

customers, partially offset by 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.

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

Costs and expenses (in thousands):

	Year Ended December 31,		Increase/(Decrease)	
	2017	2016	$	%
Cost of revenues	$ 32,830	$ 28,325	$ 4,505	16%
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	$ 71,999	$ 60,470	$ 11,529	19%

Cost of revenues increased as a percentage of total revenue to 55% for the year ended December 31, 2017 as compared to 45% 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, 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 $0.9 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.

Other (Expense) Income, 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 gain/ (loss)	$ 7,719	$ (936)	$ 8,655	100%

Other (expense) income 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

6), 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.

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 change is due to increases in costs and expenses in 2017 offset by foreign currency exchange gain of $7.7 million.

Liquidity and Capital Resources

Our capital resources were comprised of cash and cash equivalents of $9.7 million and $26.7 million as of December 31, 2018 and December 31, 2017, respectively. We had working capital of $15.8 million at December 31, 2018. Our liquidity needs have typically arisen from the funding of our new manufacturing facility, product manufacturing costs, research and development programs and the launch of new products. In the past, we have met these cash requirements through cash inflows from operations, working capital management, and proceeds from borrowings discussed in Note 6. Although the construction of our new manufacturing facility was completed in October of 2018, additional investment will be needed to prepare the facility and our employees for a prior approval inspection from the FDA. In addition, we expect to continue to incur significant expenditures for the development of new products in our pipeline, and the manufacturing and sales and marketing of our existing product. While we rely heavily on cash flows from operating activities and borrowings from outside sources to execute our operational strategy and meet our financial commitments and other short-term financial needs, we cannot be certain that sufficient capital will be generated through operations or will be available to the Company to the extent required and on acceptable terms.

The $13.2 million reduction in our cash during the twelve months ended December 31, 2018 was largely due to additional investment in the Company's new manufacturing facility located in Buena, New Jersey as evidenced by the $25.3 million increase of property, plant and equipment, net, along with the timing of our accounts receivable collections and expense payments associated with our launch of eight new products in the U.S. market. In addition, we had an accumulated deficit of $96.4 million as of December 31, 2018, and incurred a $36.3 million net loss and used $13.3 million in net cash from operating activities during the twelve months ended December 31, 2018.

On April 27, 2018, we entered into separate exchange agreements with certain holders of the 2019 Notes. The agreements gave the holders the right to exchange, in aggregate, $75.1 million of the 2019 Notes for $75.1 million of

new Convertible 4.75% Senior Notes due 2023 (the “2023 Notes”). The 2023 Notes bear a fixed interest rate of 4.75% per year, payable semi-annually with the principal payable in May 2023. At the option of the holders, the 2023 Notes are convertible into shares of our common stock, cash or a combination thereof. The initial conversion rate is $224.71 per share, subject to certain adjustments, related to either our stock price volatility, or the Company's declaration of a stock dividend, stock distribution, share combination or share split expected dividends or other anti-dilutive activities. In addition, holders will be entitled to receive additional shares of common stock for a potential increase of the conversion rate up to $280.90 per share under a make-whole provision in some circumstances. We incurred debt issue costs of $1.6 million upon issuance of the 2023 Notes.

In addition, on May 4, 2018, we filed a Registration Statement on Form S-3 ("the Form S-3") pursuant to the Securities Act of 1933, as amended. The Form S-3 registration allows us to issue, from time to time and at prices to be determined at or prior to the offering, up to $50.0 million of any combination of the securities described in the prospectus, either individually or in units should the need to raise cash arise. We did not timely file our financial statements for the quarter ended September 30, 2018. As a result, our access to offer up to $50.0 million of the identified securities was suspended for twelve months.

On December 13, 2018, we entered into a $25.0 million Revolving Credit Agreement (the "Revolver") and Term Loan Agreement (the "2023 Term Loan", and together with the Revolver, the "Senior Credit Facilities"). The Term Loan consists of (i) a $50.0 million initial term loan (the "Initial Term Loan"); (ii) a $30.0 million delayed draw term loan A (the "Delayed Draw Term Loan A") and (iii) a $15.0 million delayed draw term loan B (the "Delayed Draw Term Loan B" and, together with the Delayed Draw Term Loan A, the "Delayed Draw Term Loans"). The Initial Term Loan matures on the earlier to occur of (a) three months prior to maturity of the 2023 Notes and (b) June 13, 2024. Commitments related to undrawn amounts of the Delayed Draw Term Loan A terminate on June 30, 2019, and drawn amounts under the Delayed Draw Term Loans mature at the same time as the Initial Term Loan. The Revolver matures on the earlier to occur of (a) six months prior to the maturity of the 2023 Notes and (b) December 13, 2023. Our ability to borrow under the Revolver is subject to a borrowing base determined based upon eligible inventory, eligible equipment, eligible real estate and eligible receivables. The Senior Credit Facilities are secured by substantially all of our assets. All of our debt is subordinated to the Senior Credit Facilities. The 2023 Term Loan is subordinated to the Revolver. The Senior Credit Facilities have customary financial and non-financial covenants, including affirmative, negative and reporting covenants, representations and warranties, and events of default, including cross-defaults on other material indebtedness, as well as events of default triggered by a change of control and certain actions initiated by the FDA. The financial covenants consist of a minimum revenue test, a minimum adjusted EBITDA test and a maximum total net leverage ratio.

In December 2018 the Company used $52.8 million of proceeds from the Senior Credit Facilities to repurchase the 2019 Notes as well as $0.3 million of proceeds to pay for transaction costs. The repurchase of the 2019 Notes for is considered a debt extinguishment under ASC 470-50. The 2019 Notes are accounted for under cash conversion guidance ASC 470-20, which requires us to allocate the fair value of the consideration transferred upon settlement to the extinguishment of the liability component and the reacquisition of the equity component upon derecognition. We allocated the total amount of unamortized debt issuance costs incurred to the liability and equity components using the same proportions as the consideration transferred to extinguish the 2019 Notes. In accordance with the guidance above, we recorded $1.7 million as an extinguishment loss related to the repurchase of the 2019 Notes in the Consolidated Statement of Operations. In addition, we recorded a $2.9 million reduction of Additional Paid in Capital in connection with the extinguishment of the 2019 Notes.

In the event the Company needs liquidity beyond what is available from the Senior Credit Facilities, in order to continue normal business operations and execution of the Company's growth strategy, the Company will need to exercise its ability to significantly defer or reduce planned discretionary investments in research and development and capital projects or seek other financing alternatives. Other financing alternatives may include raising additional capital through the sale of its equity, a strategic alliance with a third party or securing additional debt. If additional acquisition and growth opportunities arise, external financing will be required.

Our operating activities used $13.3 million of cash during the year ended December 31, 2018 compared to $0.4 million of cash provided during the year ended December 31, 2017 and $0.5 million of cash used during the year ended December 31, 2016. The cash used for the year ended December 31, 2018 was mostly due to an increase in accounts receivable of $4.0 million and inventories of $1.6 million, and a reduction in accounts payable of $3.4 million, in addition to $7.3 million of interest paid on our Notes, Revolver, and Term Loans. The cash provided by operating activities for the year ended December 31, 2017 was mostly due to the collections of accounts receivable in 2017, which contributed to a net decline in accounts receivable of $6.0 million 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 $5.4 million of interest expense related to our Notes.

Consolidated revenue growth of 10% in 2018 was primarily driven by increased sales in Canada. Competitors in Canada experienced drug shortages and Teligent was able to capitalize on these opportunities, increasing sales volume

and cash flow from operating activities by $7.4 million more than anticipated. During the year some products had some production constraints which resulted in a delay in shipping of the manufactured products, this had a negative impact on the statement of operations and operating cash flows as Teligent had to absorb the cost of this delay. Overall economic conditions of the market were not favorable during 2018 as the pharmaceutical industry was under scrutiny and market pressure to not increase prices. Sales for U.S. operations were also negatively impacted due to the delay in supply from suppliers, which in turn impacted sales to our customers.

Our investing activities used $25.3 million during the year ended December 31, 2018 compared to $40.4 million and $20.1 million of cash used in the years ended December 31, 2017 and December 31, 2016, respectively. The funds used for the year ended December 31, 2018 included $25.3 million in capital expenditure, the majority of which were for the facility expansion in Buena, NJ. The funds used for the year ended December 31, 2017 included $40.4 million in capital expenditures, the majority of which were also 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 also 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.

Our financing activities provided $25.3 million of cash during the year ended December 31, 2018 compared to $0.3 million of cash provided by and no cash used or provided by financing activities in the year ended December 31, 2017 and December 31, 2016, respectively. The cash provided during the year ended December 31, 2018 consisted of proceeds from the 2021 Term Loan which was later replaced by the Senior Credit Facilities with Ares Capital Management. 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 due to principal payments on capital lease obligations offset by proceeds from the exercise of common stock warrants and options.

Off-Balance Sheet Arrangements

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

Contractual Obligations

Our contractual obligations and commitments as of December 31, 2018 are presented below. Outstanding debt and interest obligation is discussed in Note 6 of our Consolidated Financial Statements. 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 Mississauga, Canada and office and laboratory space in Tallinn, Estonia. Our remaining obligations under these leases are summarized below.

	Payments Due by Period (in thousands)				
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Short term debt obligations	$ 15,702	$ 15,702	$ —	$ —	$ —
Long term debt obligations	160,090	—	—	160,090	—
Interest on debt obligations	37,583	9,063	18,150	10,370	—
Operating Lease	3,234	573	1,244	1,217	200
Total	**$ 216,609**	**$ 25,338**	**$ 19,394**	**$ 171,677**	**$ 200**

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, 2018, 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, accounts payable and other accrued liabilities at December 31, 2018 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 recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. The Company’s revenue is recorded net of accruals for estimated chargebacks, rebates, cash discounts, other allowances, and returns. The Company derives its revenues from three types of transactions: sales of its own pharmaceutical products (Company product sales), sales of manufactured product for its customers (contract manufacturing sales), and research and product development services performed for third parties. Due to differences in the substance of these transaction types, the transactions require, and the Company utilizes, different revenue recognition policies for each. Taxes collected from customers and remitted to government authorities and that are related to the sales of the Company’s products are excluded from revenues.

Adoption of ASC Topic 606, "Revenue from Contracts with Customers”

In May 2014, the FASB issued ASU 2014-09, “Revenue from Contracts with Customers (Topic 606).” The standard, including subsequently issued amendments, replaces most existing revenue recognition guidance in U.S. GAAP. 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.

The Company performed a comprehensive review of its existing revenue arrangements as of January 1, 2018 following the five-step model. Based on the Company's analysis, there were no changes identified that impacted the amount or timing of revenues recognized under the new guidance as compared to the previous guidance. Additionally, the Company's analysis indicated that there were no changes to how costs to obtain and fulfill our customer contracts would be recognized under the new guidance as compared to the previous guidance. The impact of the adoption of this standard on the Company's Consolidated Balance Sheet, Consolidated Statement of Operations, and Consolidated Statement of Cash Flows was not material. The adoption of the new guidance impacted the way the Company analyzes, documents, and discloses revenue recognition under customer contracts beginning on January 1, 2018 and resulted in additional disclosures in the Company's financial statements.

Company Product Sales

Revenue from Company product sales is recognized upon transfer of control of a product to a customer at a point in time, generally as the Company's products are sold on an FOB destination basis and because inventory risk and risk of ownership passes to the customer upon delivery.

Company product sales are recorded net of accruals for estimated chargebacks, rebates, cash discounts, other allowances, and returns.

Revenue and Provision for Sales Returns and Allowances

As is customary in the pharmaceutical industry, the Company's product sales are subject to a variety of deductions including chargebacks, rebates, cash discounts, other allowances, and returns. Product sales are recorded net of accruals for returns and allowances ("SRA"), which are established at the time of sale. The Company analyzes the adequacy of its accruals for returns and allowances quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that an adjustment is appropriate. Accruals are also adjusted to reflect actual results. 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 Company uses a variety of methods to assess the adequacy of its returns and allowances reserves to ensure that its financial statements are fairly stated. These include periodic reviews of customer inventory data, customer contract programs, subsequent actual payment experience, and product pricing trends to analyze and validate the return and allowances reserves.

Chargebacks are one of the Company's most significant estimates for recognition of product sales. A chargeback represents an amount payable in the future to a wholesaler for the difference between the invoice price paid to the Company by its 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 validates the chargeback accrual quarterly through a review of the inventory reports obtained from its largest wholesale customers. This customer inventory information is used to establish the estimated liability for future chargeback claims based on historical chargeback and contract rates. These large wholesalers represent a majority 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.

Rebates are used for various discounts and rebates provided to customers. This account has been used for various one-time discounts given to customers. The Company reviews the percentage of products sold through these programs by reviewing chargeback data and uses the appropriate percentages to calculate the rebate accrual. Rebates are invoiced monthly, quarterly or annually and reviewed against the accruals. Other items that could be included in accrued rebates would be price protection fees, shelf stock adjustments (SSAs), or other various amounts that would serve as one time discounts on specific products.

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.

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.

Accounting Pronouncements

See Note 3 to the Consolidated Financial Statements for Recently Adopted Accounting Pronouncements and Recently Issued Accounting Pronouncements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2018, our principal debt obligation was related to our 2019 and 2023 Notes and New Senior Credit Facilities. Interest accrues at a fixed rate of 3.75% on the outstanding principal amount of the 2019 Notes and is paid semi-annually every June 15 and December 15 until the 2019 Notes mature on December 15, 2019. Interest accrues at a fixed rate of 4.75% on the outstanding principal amount of the 2023 Notes and is paid semi-annually every May 1 and November 1 until the 2023 Notes mature on May 1, 2023. Since the interest rate is fixed, we have no market risk related to the 2019 and 2023 Notes.

On December 13, 2018, pursuant to a Commitment Letter, dated November 12, 2018, between us and Ares Management LLC, we entered into: (i) a First Lien Revolving Credit Agreement, by and among us, as the borrower, certain subsidiaries of the ours, as guarantors, the lenders from time to time party thereto, and ACF Finco I LP, as administrative agent (the “Revolver Credit Agreement”) and (ii) a Second Lien Credit Agreement, by and among the Company, as the borrower, certain subsidiaries of the Company, as guarantors, the lenders from time to time party thereto, and Ares Capital Corporation, as administrative agent (the “Second Lien Credit Agreement” and, together with the Revolver Credit Agreement, the “New Senior Credit Facilities”).

The New Senior Credit Facilities consist of an asset based revolving credit facility of $25.0 million due November 2022 ("Revolver"), a term loan of $80.0 million due February 2023 (“2023 Term Loan”), and a delayed draw term loan of $15.0 million also due in February 2023 (“2023 Delayed Draw Term Loan”). The Revolver bears interest at a rate of one, two, three or six-month LIBOR plus 3.75% or base rate plus 2.75%, whereas the 2023 Term Loan and 2023 Delayed Draw Term Loan bear interest at a rate of LIBOR plus 8.75% or base rate plus 2.75% with a 24-month paid-in-kind interest option available to us should it choose to defer cash payments in order to maintain the liquidity needed to continue launching new products. All three tranches of funding are subject to market risk.

Our financial instruments include cash and cash equivalents, accounts receivable, accounts payable and 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. As of December 31, 2018, based on level 2 inputs,
the fair value of our Notes (2019 Notes and 2023 Notes) was approximately $67.6 million compared to their carrying value of $71.3 million. For description of the fair value hierarchy and the Company's fair value methodologies, see Note 3 " Summary of Significant Accounting Policies." In addition, the value of our Senior Credit Facilities was stated at carrying value at December 31, 2018. The Company believes it could obtain borrowings at December 31, 2018 with comparable terms as the December 13, 2018 Senior Credit Facilities, therefore, the carrying value approximates fair value.

At December 31, 2018, the majority 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

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, 2018, 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, 2018 (the "Evaluation Date"), because of the material weaknesses in our internal control over financial reporting described below.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act and based upon the criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("the COSO framework"). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with GAAP.

An effective internal control system, no matter how well designed, has inherent limitations, including the possibility of human error or overriding of controls, and therefore can provide only reasonable assurance with respect to reliable financial reporting. Because of its inherent limitations, our internal control over financial reporting may not prevent or detect all misstatements, including the possibility of human error, the circumvention or overriding of controls, or fraud. Effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements.

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, 2018. In making this assessment, management used the criteria set forth by the COSO framework. Based on evaluation under these criteria, management determined, based upon the existence of the material weaknesses described below, that we did not maintain effective internal control over financial reporting as of the Evaluation Date.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim financial statements would not be prevented or detected on a timely basis.

Control Environment

We did not maintain an effective control environment based on the criteria established in the COSO framework. We have identified deficiencies in the principles associated with the control environment of the COSO framework. Specifically, these control deficiencies constitute material weaknesses, either individually or in the aggregate, relating to: (i) appropriate organizational structure, reporting lines, and authority and responsibilities in pursuit of objectives, (ii) our commitment to attract, develop, and retain competent individuals, and (iii) holding individuals accountable for their internal control related responsibilities. As disclosed in the consolidated financial statements included in Item 8. "Financial Statements and Supplementary Data", these material weaknesses contributed to accounting errors.

We did not maintain an effective control environment to enable the identification and mitigation of risks of accounting errors based on the contributing factors to material weakness in the control environment, including:

•We did not attract, develop, and retain competent management, accounting, financial reporting, internal audit, and information systems personnel or resources to ensure that internal control responsibilities were performed and that information systems were aligned with internal control objectives.

•Our oversight processes and procedures that guide individuals in applying internal control over financial reporting were not adequate in preventing or detecting accounting errors.

Risk Assessment

We did not design and implement an effective risk assessment based on the criteria established in the COSO

framework. We have identified deficiencies in the principles associated with the risk assessment component of the COSO framework. Specifically, these control deficiencies constitute material weaknesses, either individually or in the aggregate, relating to: (i) identifying, assessing, and communicating appropriate objectives, (ii) identifying and analyzing risks to achieve these objectives, and (iii) identifying and assessing changes in the business that could impact our system of internal controls.

Control Activities

We did not design and implement effective control activities based on the criteria established in the COSO framework. We have identified deficiencies in the principles associated with the control activities component of the COSO framework. Specifically, these control deficiencies constitute material weaknesses, either individually or in the aggregate, relating to: (i) selecting and developing control activities and information technology that contribute to the mitigation of risks and support achievement of

objectives and (ii) deploying control activities through policies that establish what is expected and procedures that put policies into action.

The following deficiencies in control activities, among others, contributed to accounting errors or the potential for there to have been accounting errors in substantially all financial statements account balances and disclosures:

- Lack of sufficient resources within the accounting and financial reporting department to review the accounting for non-recurring complex debt transactions;
- Ineffective controls over price concessions 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 accounting and financial reporting;
- Ineffective controls over the application of accounting guidance and the Company’s policy including the allowance for doubtful accounts; and
- Ineffective controls over the transition, implementation and disclosure of the new accounting standard related to revenue recognition, specifically related to accounting for wholesaler fees, Medicaid and Medicare payments, and other rebates

Information and Communication

We did not generate and provide quality information and communication based on the criteria established in the COSO framework. We have identified deficiencies in the principles associated with the information and communication component of the COSO framework. Specifically, these control deficiencies constitute material weaknesses, either individually or in the aggregate, relating to: (i) obtaining, generating, and using relevant quality information to support the function of internal control, and (ii) communicating accurate information internally and externally, including providing information pursuant to objectives, responsibilities, and functions of internal control.

Monitoring Activities

We did not design and implement effective monitoring activities based on the criteria established in the COSO framework. We have identified deficiencies in the principles associated with the monitoring component of the COSO framework. Specifically, these control deficiencies constitute material weaknesses, either individually or in the aggregate, relating to: (i) selecting, developing, and performing ongoing evaluation to ascertain whether the components of internal controls are present and functioning, and (ii) evaluating and communicating internal control deficiencies in a timely manner to those parties responsible for taking corrective action.

The following were contributing factors to the material weaknesses in monitoring activities:

- Internal audit staffing levels were insufficient which limited our ability to effectively monitor internal controls.
- Failure to effectively communicate relevant information and internal control deficiencies to our Audit Committee for appropriate oversight, monitoring and enforcement of corrective action.
- Not communicating relevant information within our organization.

Deloitte & Touche LLP, our independent registered public accounting firm, has audited the effectiveness of our internal control over financial reporting as of December 31, 2018. Deloitte &Touche LLP's opinion, as stated in their report which appears in Item 8 of this Form 10-K, is consistent with management's report on internal control over financial reporting as set forth above.

Changes in Internal Control Over Financial Reporting

Except for the identification of the material weaknesses described above, there were no changes during the year ended December 31, 2018 in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Accounting errors corrected during the quarter were systemic to the material weaknesses previously identified by the Company.

Remediation Plan and Status

Our remediation efforts are ongoing and we will continue our initiatives to implement and document policies, procedures, and internal controls.

Remediation of the identified material weaknesses and strengthening our internal control environment will require a substantial effort throughout 2019 and beyond, as necessary. We will test the ongoing operating effectiveness of the new and existing controls in future periods. The material weaknesses cannot be considered completely remediated until the applicable controls

have operated for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

While we believe the steps taken to date and those planned for implementation will improve the effectiveness of our internal control over financial reporting, we have not completed all remediation efforts identified herein. Accordingly, as we continue to monitor the effectiveness of our internal control over financial reporting in the areas affected by the material weaknesses described above, we have and will continue to perform additional procedures prescribed by management, including the use of manual mitigating control procedures and employing any additional tools and resources deemed necessary, to ensure that our consolidated financial statements are fairly stated in all material respects. The following remediation activities highlight our commitment to remediating our identified material weaknesses:

Control Environment

We have undertaken steps to address material weaknesses in the control environment. The control environment, which is the responsibility of management, sets the tone of the organization, influences the control consciousness of its people, and is the foundation for all other components of internal control over financial reporting. Our Audit Committee and management have emphasized and continued to emphasize the importance of internal control over financial reporting, as well as the integrity of our financial statements.

Our management has taken and will continue to take steps to ensure that previously identified control deficiencies will be remediated through the implementation of uniform accounting and internal control policies and procedures with the proper oversight to promote compliance with GAAP and regulatory requirements.

To date, we hired a new senior leader in one of our foreign affiliates who, among other responsibilities, ensures customer contract terms and price concessions are reviewed with key members of the accounting and financial reporting department on a timely basis to appropriately reflect in the financial records. In addition, we hired new accounting and financial reporting team members and engaged external resources with significant experience with systems similar to the Company's ERP system and infrastructure to provide additional capacity, analytical and functional capabilities, and cross-training. The addition of skilled personnel will allow us to select and develop appropriate policies, procedures, and controls to strengthen our control environment. Management will continue to evaluate and hire additional resources within our accounting and financial reporting, internal audit, and information technology functions with the appropriate experience, certifications, education, and training for key financial reporting and accounting positions. Management believes this will reduce the risk of a material misstatement resulting from the material weaknesses described above. However, it will require a period of time to determine the operating effectiveness of these newly implemented internal controls over financial reporting.

Risk Assessment

We have begun implementing a process for performing detailed reviews of financial records at our corporate headquarters for the purpose of identifying and correcting accounting errors. We will continue to enhance risk assessment procedures and conduct a comprehensive risk assessment to enhance overall compliance. The results of this effort are expected to enable us to effectively identify, develop, and implement controls and procedures to address risks.

Control Activities

We have begun the process of redesigning and implementing internal control activities. We also plan to establish policies and procedures and enhance corporate oversight over process-level controls and structures to ensure that there is appropriate assignment of authority, responsibility, and accountability to enable remediating our material

weaknesses.

Information and Communication

We have taken various steps to enhance our practices as it relates to information and communication, including conducting periodic reviews of the ERP system access to ensure appropriate segregation of duties exists for functional and administrative users and establishing policies and procedures addressing the internal control framework and operating effectiveness of the Company's third-party ERP service provider.

Monitoring Activities

In addition to the items noted above, as we continue to evaluate, remediate, and improve our internal control over financial reporting, executive management may elect to implement additional measures to address control deficiencies or may determine that the remediation efforts described above require modification. Executive management, in consultation with and at the

direction of our Audit Committee, will continue to assess the control environment and the above-mentioned efforts to remediate the underlying causes of the identified material weaknesses, including through the following:

• We will increase internal audit, finance, accounting, and information technology staffing levels.
• We are also developing effective communication plans relating to, among other things, identification of deficiencies and recommendations for corrective actions. These plans will apply to all parties responsible for remediation.

Inherent Limitations on Effectiveness of Controls

Management, including our CEO, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, misstatements, errors, and instances of fraud, if any, within our organization have been or will be prevented or detected.

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls also can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, internal controls may become inadequate as a result of changes in conditions, or through the deterioration of the degree of compliance with policies or procedures.

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 2019 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 2019 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 2019 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 2019 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 2019 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).
(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 SARL (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed October 1, 2014).
(10.13)	Asset Purchase Agreement dated as of September 30, 2014, by and between IGI Laboratories, Inc. and Valeant Pharmaceuticals North America, LLC and Valeant Pharmaceuticals Luxembourg SARL

	(incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed October 1, 2014).
(10.14)+	Asset Purchase Agreement dated as of September 24, 2014, by and between IGI Laboratories, Inc. and AstraZeneca Pharmaceuticals LP (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 10-Q, filed November 13, 2014).
(10.15)	Credit Agreement dated as of November 18, 2014, by and among IGI Laboratories, Inc., Igen, Inc., and IGI Labs, Inc. as Borrowers, the other Persons party thereto that are designated as Credit Parties, General Electric Capital Corporation as Agent for all Lenders, GE Capital Bank as a Lender, and the other financial institutions party thereto as Lenders (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed November 24,

	2014).
(10.16)	Guaranty and Security Agreement dated as of November 18, 2014, by and among IGI Laboratories, Inc., Igen, Inc., and IGI Labs, Inc. as Borrowers and each other Grantor from time to time party thereto in favor of General Electric Capital Corporation as Agent (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed November 24, 2014).
(10.17)	Purchase Agreement dated December 10, 2014, by and between IGI Laboratories, Inc. and the initial purchasers set forth on Schedule 1 thereto (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed December 17, 2014).
(10.18)	Second Amendment to Credit Agreement, dated as of August 14, 2015, by and among Teligent, Inc., Igen, Inc. and

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

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

(10.21)	Asset Purchase Agreement, dated October 12, 2015, between IGI Laboratories, Inc. and Alveda Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed October 13, 2015).
(10.22)	Asset Purchase Agreement, dated October 12, 2015, between IGI Laboratories, Inc. and Alveda Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed October 13, 2015).
(10.23)	Contribution Agreement, by and between the Teligent, Inc. and Teligent Luxembourg S.à.r.l., dated as of November 13, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed November 16, 2015).
(10.24)	Loan Agreement, by and between Teligent, Inc. and Teligent Luxembourg S.à.r.l., dated as of November 13,

	2015 (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed November 16, 2015).
(10.25)	Loan Agreement, by and between Teligent, Inc. and Teligent Canada Inc., dated as of November 13, 2015 (incorporated by reference to Exhibit 10.3 to the Company's Report on Form 8-K, filed November 16, 2015).
(10.26)	Distribution Agreement, by and between Teligent OÜ and Teligent Canada Inc., dated as of November 13, 2015 (incorporated by reference to Exhibit 10.4 to the Company's Report on Form 8-K, filed November 16, 2015).
(10.27)	First Amendment to Asset Purchase Agreement, by and between Teligent, Inc. and AstraZeneca Pharmaceuticals, LP, dated as of November 30, 2015 (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed December 4,

	2015).
(10.28)	First Amendment to Asset Purchase Agreement, dated December 10, 2015, by and between Concordia Pharmaceuticals Inc., S.à.r.l., Barbados Branch, on the one hand, and Teligent, Inc. and Teligent Jersey Limited, on the other hand (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed December 15, 2015).
(10.29)	Trademark Assignment Agreement, dated December 10, 2015, by and between Concordia Pharmaceuticals Inc., S.à.r.l., Barbados Branch, on the one hand, and Teligent Jersey Limited, on the other hand (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K, filed December 15, 2015).
(10.30)#	Teligent, Inc. 2016 Equity Incentive Plan, as amended (incorporated by reference to

	Exhibit 10.1 to the Company's Report on Form 8-K, filed August 9, 2018.
(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).
(10.33)#	Indenture, dated May 1, 2018, by and between the Company and Wilmington Trust, National Association, as trustee (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed May 2, 2018).
(10.34)#	Form of Exchange Agreement Related to 4.75%

	Convertible Senior Notes (incorporated by reference to Exhibit 99.1 to the Company's Report on Form 8-K, filed May 2, 2018).
(10.35)#	Credit Agreement, dated June 1, 2018, by and among the Company, the guarantors party thereto from time to time, each lender from time to time party thereto and Cantor Fitzgerald Securities (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed June 5, 2018).
(10.36)#	Commitment Letter, dated November 12, 2018, by and between the Company and Ares Management LLC (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed November 13, 2018).

(10.37)#	First Lien Revolving Credit Agreement, dated December 13, 2018, by and among the Company, certain Subsidiaries thereof, the Lenders from time to time party thereto, and ACF Finco LLP, as Administrative Agent (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K, filed December 14, 2018).
(10.38)#	Second Lien Credit Agreement, dated December 13, 2018, by and among the Company, certain Subsidiaries thereof, the Lenders from time to time party thereto, and Ares Capital Corporation, as Administrative Agent (incorporated by reference to Exhibit 10.2 to the Company's Report as Form 8-K, filed December 14, 2018).
(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.
(23.2)*	Consent of Deloitte & Touche 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.
(33.1)*	Separation Agreement, dated May 7, 2018, by and between the Company and Jenniffer Collins (incorporated by reference to Exhibit 33.1 to the Company's Report on Form 10-Q, filed May 15, 2018).
(101)*	The following financial information from this Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL (Extensible Business Reporting Language) and furnished electronically herewith: (i) the Consolidated Statements of Operations; (ii) the Consolidated Balance Sheets; (iii) the Consolidated Statements of Cash Flows; and (iv) the Notes to Consolidated Financial Statements,

tagged as blocks
of text.

*Filed herewith.
#Indicates management contract or compensatory plan.
+Portions of this Exhibit were omitted and filed separately with the Secretary of the SEC pursuant to a request for confidential treatment that has been granted by the SEC.

SIGNATURES

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

Teligent, Inc.

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

Date: April 1, 2019

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)	April 1, 2019
/s/ Damian Finio Damian Finio	Chief Financial Officer (Principal Financial Officer)	April 1, 2019
/s/ Steven Koehler Steven Koehler	Director	April 1, 2019
/s/ James Gale	Director	April 1,

		2019
James Gale		
/s/ Bhaskar Chaudhuri	Director	April 1, 2019
Bhaskar Chaudhuri		
/s/ John Celentano	Director	April 1, 2019
John Celentano		
/s/ Carole Ben-Maimon	Director	April 1, 2019
Carole Ben-Maimon		
/s/ Thomas Sabatino	Director	April 1, 2019
Thomas Sabatino		

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Teligent, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Teligent, Inc. and subsidiaries (the "Company") as of December 31, 2018, and the related consolidated statement of operations, comprehensive income (loss), stockholders' equity, and cash flows, for the year ended December 31, 2018, and the related notes and the schedule listed in the Index to Consolidated Financial Statements (collectively referred to as the "financial statements "). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We have also 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, 2018, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated April 1, 2019 expressed an adverse opinion on the Company's internal control over financial reporting.

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 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 the financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 audit 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 audit provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Parsippany, New Jersey

April 1, 2019

We have served as the Company’s auditor since 2018.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Teligent, Inc.

Opinion on the Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Teligent, Inc and subsidiaries (the "Company") as of December 31, 2018, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, because of the effect of the material weaknesses identified below on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2018, of the Company and our report dated April 1, 2019 expressed an unqualified opinion on those financial statements.

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 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, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may

deteriorate.

Material Weaknesses

A material weakness is a deficiency, or a 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:

Control Environment - control deficiencies constituting material weaknesses, either individually or in the aggregate, relating to: (i) appropriate organizational structure, reporting lines, and authority and responsibilities in pursuit of objectives, (ii)

commitment to attract, develop, and retain competent individuals, and (iii) holding individuals accountable for their internal control related responsibilities.

Risk Assessment - control deficiencies constituting material weaknesses, either individually or in the aggregate, relating to: (i) identifying, assessing, and communicating appropriate objectives, (ii) identifying and analyzing risks to achieve these objectives, and (iii) identifying and assessing changes in the business that could impact the system of internal controls.

Control Activities - control deficiencies constituting material weaknesses, either individually or in the aggregate, relating to: (i) selecting and developing control activities and information technology that contribute to the mitigation of risks and support achievement of objectives and (ii) deploying control activities through policies that establish what is expected and procedures that put policies into action.

Information and Communication - control deficiencies constituting material weaknesses, either individually or in the aggregate, relating to: (i) obtaining, generating, and using relevant quality information to support the function of internal control, and (ii) communicating accurate information internally and externally, including providing information pursuant to objectives, responsibilities, and functions of internal control.

Monitoring - control deficiencies constituting material weaknesses, either individually or in the aggregate, relating to: (i) selecting, developing, and performing ongoing evaluation to ascertain whether the components of internal controls are present and functioning, and (ii) evaluating and communicating internal control deficiencies in a timely manner to those parties responsible for taking corrective action.

These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements as of and for the year ended December 31, 2018, of the Company, and this report does not affect our report on such financial statements.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey

April 1, 2019

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Teligent, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Teligent, Inc. and subsidiaries (the "Company") as of December 31, 2017, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for the years ended December 31, 2017 and 2016, and the related notes and schedule II (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and the results of its operations and its cash flows for the years ended December 31, 2017 and 2016, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We served as the Company's auditor from 2010 to 2018.

EISNERAMPER LLP
Iselin, New Jersey
March 19, 2018

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

	12/31/2018		12/31/2017	
ASSETS				
Current assets:				
Cash and cash equivalents	$	9,705	$	26,692
Restricted cash	2,892		—	
Accounts receivable, net of allowance for doubtful accounts of $2,636 and $2,185, as of December 31, 2018 and December 31, 2017, respectively	16,120		12,742	
Inventories	16,296		16,075	
Prepaid expenses and other receivables	3,373		3,622	
Total current assets	48,386		59,131	
Property, plant and equipment, net	91,775		68,355	
Intangible assets, net	48,375		56,017	
Goodwill	470		471	
Other	1,886		611	
Total assets	$	190,892	$	184,585
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	$	5,933	$	10,595
Accrued expenses	9,842		8,101	
Deferred income, current	2,426		—	
Convertible 3.75% Senior Notes, net of debt discount and debt issuance costs (face of $15,702 as of December 31, 2018)	14,411		—	
Total current liabilities	32,612		18,696	
Convertible 3.75% Senior Notes, net of	—		120,977	

debt discount and debt issuance costs (face of $143,750 as of December 31, 2017)				
Convertible 4.75% Senior Notes, net of debt discount and debt issuance costs (face of $75,090 as of December 31, 2018)	56,909		—	
Revolver, net of debt issuance costs (face of $15,000 as of December 31, 2018)	15,000		—	
2023 Term Loan, net of debt issuance costs (face of $70,000 as of December 31, 2018)	67,662		—	
Deferred tax liability	215		159	
Other long term liabilities	73		—	
Total liabilities	172,471		139,832	
Commitments and Contingencies				
Stockholders' equity:				
Common stock, $0.01 par value, 100,000,000 shares authorized; 53,774,221 and 53,400,281 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	557		554	
Additional paid-in capital	116,864		106,312	
Accumulated deficit	(96,350)		(60,094)	
Accumulated other comprehensive loss, net of taxes	(2,650)		(2,019)	
Total stockholders' equity	18,421		44,753	
Total liabilities and stockholders' equity	$	190,892	$	184,585

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

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TELIGENT, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
For the years ended December 31, 2018, 2017 and 2016
(in thousands, except shares and per share information)

	2018		2017		2016	
Revenue, net	$	65,865	$	60,202	$	63,012
Costs and Expenses:						
Cost of revenues	43,480		32,830		28,325	
Selling, general and administrative expenses	23,408		19,904		15,005	
Product development and research expenses	14,076		19,265		17,140	
Total costs and expenses	80,964		71,999		60,470	
Operating (loss) income	(15,099)		(11,797)		2,542	
Other (Expense) Income:						
Foreign currency exchange (loss) gain	(3,371)		7,719		(936)	
Debt partial extinguishment of 2019 Notes	(4,235)		—		—	
Debt extinguishment of 2021 Term Loan	(1,315)		—		—	
Interest and other expense, net	(12,298)		(11,198)		(13,304)	
Loss before income tax expense	(36,318)		(15,276)		(11,698)	
Income tax (benefit) expense	(62)		(85)		287	
Net loss attributable to common	$	(36,256)	$	(15,191)	$	(11,985)

stockholders						
Basic and diluted loss per share	$	(0.68)	$	(0.28)	$	(0.23)
Weighted average shares of common stock outstanding:						
Basic and diluted	53,592,930		53,323,954		53,078,158	

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, 2018, 2017 and 2016
(in thousands)

	2018	2017	2016
Net loss	$ (36,256)	$ (15,191)	$ (11,985)
Other comprehensive loss, net of tax			
Foreign currency translation adjustment	(631)	(414)	(1,475)
Other comprehensive loss	(631)	(414)	(1,475)
Comprehensive loss	$ (36,887)	$ (15,605)	$ (13,460)

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

TELIGENT, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended December 31, 2018, 2017 and 2016

	2018	2017	2016
Cash flows from operating activities:			
Net loss	$ (36,256)	$ (15,191)	$ (11,985)
Reconciliation of net loss to net cash provided by (used in) operating activities:			
Depreciation of fixed assets	2,579	1,711	946
Gain on sale of assets	(20)	—	—
Provision for write down of inventory	1,363	2,132	1,400
Provision for bad debt	452	1,767	327
Issuance of stock to consultant	102	—	189
Stock based compensation	1,970	3,295	2,999
Amortization of debt costs and debt discount	9,226	9,586	8,427
Amortization of intangibles	3,096	2,930	2,833
Deferred income taxes	73	—	—
Foreign currency exchange loss (gain)	3,371	(7,719)	936
Partial extinguishment of 3.75% senior notes	4,235	—	—
Extinguishment of 2021 term loan	1,315	—	—
Loss on impairment of intangible assets	1,924	113	16
Changes in operating assets and liabilities:			
Accounts receivable			