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

FORM 10-K

(Mark One)

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

For the fiscal year ended **December 31, 2019**

OR

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

For the transition period from _____ to _____

Commission file number: **001-08568**

Teligent, Inc.

(Formerly IGI Laboratories, Inc.)

(Exact name of registrant as specified in its charter)

Delaware	**01-0355758**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
105 Lincoln Ave., Buena, NJ	**08310**
(Address of principal executive offices)	*(Zip Code)*

Registrant's telephone number, including area code **(856) 697-1441**

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading symbol(s)	Name of each exchange on
Common Stock, Par Value $0.01 Per Share	TLGT	The Nasdaq Stock Market

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

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

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

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

Indicate by check mark 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:

Large accelerated filer☐ Accelerated filer ☐
Non-accelerated filer☒
Smaller reporting company ☒
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 ☒

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 $27.4 million.

As of March 25, 2020, the registrant had 53,899,495 shares of common stock outstanding.

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 19, 2020.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements regarding us and our business, financial condition, results of operations and prospects within the meaning of Section 27A of the Securities Act of 1933 (Securities Act), and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

In some cases, you can identify forward-looking statements by terminology, such as “goals,” “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” “may,” “could,” “should,” “would,” “predicts,” “appears,” “projects,” or the negative of such terms or other similar expressions. Factors that could cause or contribute to differences in results and outcomes from those in our forward-looking statements include, without limitation, those discussed in this Current Report on Form 10-K, as well as those discussed in our other Securities and Exchange Commission ("SEC") filings. We undertake no obligation to (and expressly disclaim any obligation to) revise or update any forward-looking statements made herein whether as a result of new information, future events or otherwise. However, you should consult any further disclosures we may make on these or related topics in our reports on Form 8-K or Form 10-Q filed with the SEC.

The following discussions should be read in conjunction with the sections of this Report entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors.”

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, branded generic and generic injectable pharmaceutical products in the United States and Canada. In the United States we are currently marketing 38 generic topical pharmaceutical products and 4 branded generic pharmaceutical products. In Canada, we sell over 32 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.

We have two platforms for growth:

- Developing, manufacturing and marketing a portfolio of generic pharmaceutical products under our own or a private 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 primary 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 a more diversified strategic growth.

Teligent was recognized by the FDA as one of the top 15 generic companies to receive Abbreviated New Drug Application ("ANDA") approvals in 2018. In 2019, we submitted one ANDA. We currently have 16 ANDAs submitted singly and 2 ANDAs that were submitted with partners are pending at the FDA. Additionally, we have 2 ANDs pending before Canada's food and drug regulatory authority. We have an additional 45 product candidates at various stages of our development pipeline.

We expect to continue to expand our presence in the generic topical pharmaceutical market through the filing of additional ANDAs and the subsequent launch of products as these applications are approved. We received five approvals from our internally developed pipeline of topical generic products in 2019. We intend to continue to submit further ANDAs to the FDA and abbreviated new drug submissions ("ANDS") to Health Canada in 2020, although the typical timelines for submission and approval may be adversely impacted by the current COVID-19 pandemic. We continue to seek to license or acquire further products, intellectual property, or pending applications to expand our portfolio. We expect to accelerate our growth through the creation of unique opportunities from the acquisition of additional intellectual property and/or the expansion of the use of our existing intellectual property. We are also exploring the options to monetize certain of our non-core assets.

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 has increased our manufacturing capability for topical products and, upon FDA approval, will also enable the production of sterile injectable products in both vial and ampule presentations. We have utilized 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. Through December 31, 2019 the Company has incurred approximately $88.3 million for this project and is currently substantially complete with construction. 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. The expansion was implemented in order to secure Teligent's long-term growth in manufacturing and marketing injectable Pharmaceutical products for sale in the U.S.

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 completion 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 14 employees 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 relationships, 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 32 products. Teligent continues to transition these products to distribute them under a Teligent Canada label.

Teligent OÜ. Teligent OÜ currently has 15 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.

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 16 ANDA filings that Teligent has pending with the FDA totals approximately $1.06 billion per annum. 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 2020 to the extent the COVID-19 pandemic allows for the submission of new drug applications. We also have 45 additional product candidates in various stages of development.

As part of our growth strategy, we also seek opportunities to acquire additional products and ANDAs or ANDSs. On February 1, 2013, we acquired assets and intellectual property, including an approved ANDA, for econazole nitrate cream 1%, which we launched under our label in September 2013. On September 24, 2014, we acquired from AstraZeneca previously approved ANDAs and NDAs associated with 18 products, 17 of which are injectable products and one non-injectable product for pain management. On September 30, 2014, we acquired previously marketed and approved ANDAs associated with two ophthalmic products from Valeant Pharmaceuticals LLC and Valeant Pharmaceuticals Luxembourg SARL, or Valeant, in addition to the exclusive right to acquire three additional previously marketed and approved injectable products from Valeant. In November 2014, we completed the purchase of one of those three optioned injectable products and its related NDA from Valeant. In March 2015, we completed the purchase of the final two optioned injectable products and their related NDAs from Valeant.

On November 13, 2015, we formed Teligent Canada, and completed the acquisition of Alveda. Teligent Canada had 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 32 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 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 the 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 38 topical products under our own label. We have received FDA approvals for 38 topical generic products from

our internally developed pipeline. In our topical pipeline, we have 18 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 2020. 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 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 generic pharmaceutical products in our pipeline. On November 26, 2019, the FDA issued us a Warning Letter following an inspection of our manufacturing facility at 105 Lincoln Avenue, Buena, New Jersey, that identified several cGMP violations. We are continuing to work diligently to remediate all issues cited by the FDA and hope to close out this inspection in the coming months.

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 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 began one project as part of the complex portfolio of our TICO strategy. Our partner filed the ANDA in the second quarter of 2017 for a generic version of an oral product that targets an orphan disease and received a complete response letter from the FDA in the third quarter of 2018. The Company responded to the FDA's complete response letter in 2019, but received a second complete response letter on December 23, 2019. The response to this CRL was submitted on January 21, 2020. 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. The intent of this opportunity is to provide patients with a lower cost alternative of an approved orphan 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 32 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, 2019, and 2018, 43% and 54% 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, 2019, Cardinal accounted for 22% of our accounts receivable, ABC accounted for 11% of our accounts receivable, and McKesson accounted for 25% of our accounts receivable. As of December 31, 2018, Cardinal accounted for 19% of our accounts receivable, McKesson accounted for 30% of our accounts receivable, and ABC accounted for approximately 19% 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, results of operations and cash flows. There are generally three major negotiating entities in the US market. The Walgreens Boots Alliance Development (WBAD), which consists of Walgreens, AmerisourceBergen's PRxO Generics program, and Econdisc members. Red Oak Sourcing which consists of CVS and Cardinal's source program. Finally, ClarusOne which 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, results of operations and cash flows. 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, 2019, approximately 54% of our contract services revenue was derived from pharmaceutical customers, as compared to 79% of total contract services revenue for the year ended December 31, 2018. None of our contract manufacturing services customers represented 10% of total revenue for the years ended December 31, 2019 or December 31, 2018.

Concentration of Risk. In 2019, we had sales to two customers which accounted for more than 10% of our total revenue. These customers had sales of $17.6 million and $9.6 million respectively and represented 41% of total revenues in aggregate. Accounts receivable related to these two customers represented 31% of total accounts receivable as of December 31, 2019. 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 represented 30%, 19% and 19%, respectively, or 68% of all accounts receivable as of December 31, 2018.

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, 2019, domestic net revenues were $48.4 million and foreign net revenues

were $17.5 million. As of December 31, 2019, domestic net assets were $154.3 million and foreign assets were $52.6 million. 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 assets were $132.7 million and foreign assets were $58.2 million.

Our Products

Diflorasone Diacetate Ointment USP 0.05% accounted for 15% of the Company's total revenues in fiscal 2019. There was no product which individually accounted for more than 10% of the total revenues in 2018.

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

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 Propionate 0.05%	Lotion	2oz, 4oz	Clobetasol	Topical Corticosteroid
Clobetasol Propionate 0.05%	Gel	15g, 30g, 60g	Embeline®	Topical Corticosteroid
Clobetasol Propionate 0.05%	Ointment	15g, 30g, 45g, 60g	Temovate Ointment	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
Desonide 0.05%	Ointment	15g, 60g	Desonide Ointment	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 0.1%	Cream	30g, 60g, 120g	Vanos	Topical Corticosteroid
Fluocinonide 0.05%	Cream	15g, 30g, 60g, 120g	Fluocinonide Cream	Topical Corticosteroid
Fluocinonide 0.05%	Topical Solution	20mL, 60mL	Lidex	Topical Corticosteroid
Flurandrenolide 0.05%	Ointment	15g, 30g, 60g	Cordran®	Topical Corticosteroid
Gentamicin Sulfate 0.1%	Cream	15g, 30g	Garamycin Cream	Topical Anti-infective
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
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
Dorzolamide (2)	0.02	Opthalmic Solution	5 mL	Trusopt	ANDS	Elevated Intraocular Pressure Therapy (Topical Carbonic Anhydrase Inhibitor)
Dorzolamide & Timolol (2)	2% Dorzolamide and 0.5% Timolol	Opthalmic Solution	5 ml & 10 mL	Cosopt	ANDS	Elevated Intraocular Pressure Therapy (Topical Carbonic Anhydrase Inhibitor and Topical Beta-Adrenergic Blocking Agent)
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 Hydrochloride	10 mg, 200 mg, 1 g	Injectable	10 mg, 200 mg, 1 g vial	Gemzar®	ANDS	Antineoplastic agent
Gentamicin Sulfate	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
Latanoprost (2)	50 mcg/mL	Opthalmic Solution	2.5 mL	Xalatan	ANDS	Prostaglandin F2α analogue
Latanoprost & Timolol (2)	50 mcg / mL Latanoprost and	Opthalmic Solution	2.5 mL	Xalacom	ANDS	Elevated Intraocular Pressure Therapy Prostaglandin F2α Analogue and Beta-adrenergic Receptor Blocker

Product	Strength	Formulation	Presentations	Brand equivalent	Dossier type held by Teligent	Therapeutic Classification
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.
(2) Cross-licensed products registered under Teligent Canada Inc.

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 facilities in Buena, New Jersey and Estonia. 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 $10.8 million and $14.1 million in R&D expenses in 2019 and 2018, respectively.

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 available under various provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). 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 (i.e., an

RLD) 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 in a human patient. 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 the relevant RLD, 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 (i.e., orphan drug exclusivity) or the sponsor conducts pediatric studies in accordance with FDA requirements.

Supplemental ANDAs are required to secure FDA 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, which are continuously changing and evolving.

In addition to generic products that are approved for marketing via ANDAs, Section 505(b)(2) of the FD&C Act permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. Unlike the ANDA pathway used for bioequivalent versions of brand products, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness.

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.

FDASIA also included the Generic Drug User Fee Act (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 to improve the FDA's communications and feedback with industry.

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

In August 2017, Congress passed and the President signed the FDA Reauthorization Act (FDARA). Among other provisions, FDARA included the second iteration of GDUFA, or "GDUFA II," to reauthorize the collection of these user fees from industry for another 5 years, i.e., through September 2022. GDUFA II also made significant changes to the generic drug user fee program, including eliminating the fee for Prior Approval Supplements and creating a new Generic Drug Applicant Annual Program Fee, assessed based on the number of approved ANDAs owned by a company and its affiliates. The new Annual Program Fee is expected to account for approximately 62% of fees collected by FDA under GDUFA. In exchange, GDUFA II implements a number of elements to enhance communication between FDA and industry throughout the ANDA review process, thereby improving predictability and transparency and promoting the efficiency and effectiveness of the generic drug review process.

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 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 five dominant companies in the injectable generic drug market in the United States consist of Grifols USA, Fresenius Kabi USA, Pfizer, Par and Hikma. 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. The expanded facility has increased our manufacturing capability for topical products and will also enable the production of sterile injectable products in both vial and ampule presentations upon FDA approval. 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 are using this facility expansion as an opportunity to secure our long-term growth in manufacturing and marketing injectable in the US and to upgrade and improve the degree of automation and capacity in our existing topical production suite.

We operate our facility in accordance with cGMP. Our facility is registered with the FDA as a drug establishment. 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. On November 26, 2019, the FDA issued us a Warning Letter following an inspection of our manufacturing facility at 105 Lincoln Avenue, Buena, New Jersey, that identified several cGMP violations. We are continuing to work diligently to remediate all issues cited by the FDA and hope to close out this inspection in the coming months.

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, 2019, we had a total of 252 full-time employees, including 14 full-time employees in Canada and 15 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. It is not possible to predict or identify all risk factors that could impact us. For example, the current pandemic related to the COVID-19 coronavirus is causing a dramatic negative impact on the health of citizens globally which has negatively affected the economies and markets around the world. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also 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

Our business may be adversely affected by the recent coronavirus outbreak.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China. In January 2020, this coronavirus spread to other countries, including the United States, and efforts to contain the spread of this coronavirus intensified. The outbreak and any preventative or protective actions that governments or we may take in respect of this coronavirus may result in a period of business disruption, reduced customer traffic and reduced operations. Any resulting financial impact cannot be reasonably estimated at this time but may materially affect our business, financial condition, results of operations, and cash flows. The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

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. The equity and lending markets have been and will most likely continue to be negatively impacted for an unknown period of time due to the COVID-19 pandemic.

There is substantial doubt about our ability to continue as a going concern.

The following negative conditions and events raise substantial doubt about our ability to continue as a going concern as of December 31, 2019:

We incurred significant losses and generated negative cash flows from operations in recent years and expect to continue to incur losses and generate negative cash flow for the foreseeable future. As a result, we had an accumulated deficit of $121.5 million. total principal amount of outstanding borrowings of $214.0 million, and limited capital resources to fund ongoing operations at December 31, 2019. Our available capital resources may not be sufficient for us to continue to meet our obligations as they become due over the next twelve months if we cannot improve our operating results or increase our operating cash inflows. In the event these capital resources are not sufficient, we may need to raise additional capital through the sale of equity or debt securities, enter into strategic business collaboration agreements with other companies, seek other funding facilities, or sell assets. However, we cannot provide assurances that additional capital will be available on acceptable terms or at all. Moreover, if we are unable to meet our obligations when they become due over the next twelve months through our available capital resources, or obtain new sources of capital when needed, we may have to delay expenditures, reduce the scope of manufacturing operations, reduce or eliminate one or more of our development programs, make significant changes to our operating plan, or cease operations.

We are subject to certain financial covenants as set forth in the April 6, 2020 amendments to the Senior Credit Facilities. These financial covenants include a trailing twelve months ("TTM") Minimum Revenue covenant that is required to be met each quarterly period from March 31, 2020 through December 31, 2020, a TTM Minimum Adjusted EBITDA that is required to be met each quarterly period from March 31, 2021 through maturity, and a minimum liquidity covenant tested at all times through the term of the agreement. These amendments supersede the financial covenants included in the original and amended agreements disclosed in Note 6 – Debt. In the event that we are unable to comply with these covenants, or obtain a waiver from our lenders, the lender shall have the right, but not the obligation, to permanently reduce the commitment in whole or in part or to declare all or any portion of the outstanding balance due and payable. Furthermore, in the event that outstanding balances under the Ares Credit agreements are declared due and payable by the lender, the lenders of the 2023 Series A and Series B Unsecured Convertible Notes shall have the right, but not the obligation, to declare all of the outstanding balance due and payable as well. We do not currently have available liquidity to repay these outstanding borrowings in the event of a default. If we are unable to raise additional capital to meet these obligations, we may have to seek other strategic alternatives, including ceasing our operations.

In June 2019, we received a de-listing notice from the NASDAQ due to our share price being below $1.00 for 30 consecutive trading days. The notice specified that our share price must trade above $1.00 per share for ten consecutive trading days prior to December 2, 2019 in order to prevent our common stock from being de-listed. For the 180 days preceding December 2, 2019, our share price remained below $1.00. We requested a second 180-day extension. NASDAQ denied our request and we chose to file for an appeal. We were granted a hearing date for the end of January 2020. Subsequent to the appeal hearing, NASDAQ set a deadline of April 17, 2020 for us to regain compliance with NASDAQ's continuing listing requirements. In early March 2020, the COVID-19 global pandemic triggered a significant decline in global capital markets, including NASDAQ. In light of this significant decline, we requested NASDAQ to reconsider the April 17, 2020 deadline. NASDAQ agreed to our request and set a new deadline to regain compliance by June 1, 2020. In January 2020, our Board of Directors and shareholders approved a reverse stock split in the range of any whole number between five (5) and ten (10) to one (1). While we believe that the reverse stock split will ultimately increase our share price above $1.00 for the required ten consecutive trading days, we can provide no assurances that our shares will trade above $1.00 per share for the required time period. A de-listing from the NASDAQ would be a "Fundamental Change" under the Company's 2023 Series A and Series B Unsecured Convertible Notes which triggers a right by the holders to require the Company repurchase the Convertible Notes. In such an event, the Company would need to seek financing to repurchase the Convertible Notes and there is no guarantee that such financing would be available or on terms acceptable to the Company. If noteholders demanded a repurchase of the notes and the Company could not finance the repurchase, it would be in default under the Indentures governing the Convertible Notes, and in that event the lenders of the Ares Credit agreements would have the right, but not the obligation, to declare all of the outstanding balance under those agreements due and payable as well. Therefore, in the event of the Company's shares are de-listed from the NASDAQ, the Company would likely have to seek some combination of waivers from its lenders and noteholders and seek new capital through the sale of equity or debt securities. If the Company is unable to obtain such waivers or raise new capital to meet these obligations if they become due, it may have to seek other strategic alternatives, including ceasing operations.

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. We have two customers that accounted for 41% of our revenue for the year ended December 31, 2019, and three of our customers accounted for an aggregate of 54% of our revenue for the year ended December 31, 2018. The loss of one or more of these customers could have a significant impact on our revenues and harm our business, results of operations and cash flows.

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 15% of our revenue for the year ended December 31, 2019. 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 are therefore more subject to direct 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.

For example, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or the “CREATES Act.” The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a Risk Evaluation and Mitigation Strategy, or REMS, for certain products, to deny generic product developers access to samples of brand products. Because generic product developers like our company need samples to conduct bioequivalence testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on “commercially reasonable, market-based terms.” Whether and how generic product developers will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on the market entry or timeline for our future commercial products are unknown.

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. The recent COVID-19 pandemic may delay our applications in both submissions and approvals.

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.

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 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, results of operations and cash flows. The recent COVID-19 pandemic may introduce additional challenges in the retention and hiring of key personnel.

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.

The recent COVID-19 pandemic may introduce new challenges in sourcing raw materials for our products either from our existing or new suppliers and may negatively influence the cost of these raw materials.

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. The recent COVID-19 pandemic may create local issues for our single source API suppliers and introduce delays in our manufacturing process.

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, 2019, and remaining costs accrued at December 31, 2019 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 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. On November 26, 2019 FDA issued us a Warning Letter following an inspection of our manufacturing facility at 105 Lincoln Avenue, Buena, New Jersey, that identified several cGMP violations. We are continuing to work diligently to remediate all issues cited by the FDA and hope to close out this inspection in the coming months.

The recent COVID-19 pandemic has introduced additional strain on the FDA. We are unable to fully understand the impact this may cause on regulations or the related timeframes pertaining to communication with the FDA.

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 USP, 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 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.

The recent COVID-19 pandemic has introduced additional strains on Health Canada. We are unable to fully understand the impact this may cause on regulations or the related timeframes pertaining to communication with Health Canada.

Inadequate resources 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.

The introduction of the recent COVID-19 pandemic has increased the strain on the FDA, SEC and other government agencies which may increase the likelihood of delays in normal business functions.

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. In May 2016, the EU Parliament adopted the comprehensive General Data Privacy Regulation, or the GDPR to, among other things, impose more stringent data protection requirements for processors and controllers of personal data and provide for greater penalties and fines for noncompliance, including fines in amounts up to €20 million or 4% of total worldwide annual turnover, whichever is higher. The GDPR became fully effective in May 2018. In addition, in 2018, California adopted a new privacy law (effective on January 1, 2020) that borrows heavily from the GDPR. Complying with the enhanced obligations imposed by the GDPR and other applicable international and US privacy laws and regulations may result in significant costs to our business and require us to amend certain of our business practices. Further, enforcement actions and investigations by regulatory authorities related to data security incidents and privacy violations continue to increase. The future enactment of more restrictive laws, rules or regulations and/or future enforcement actions or investigations could have a materially adverse impact on us through increased costs or restrictions on our businesses, and noncompliance could result in regulatory penalties and significant legal liability.

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. The recent COVID-19 pandemic has introduced greater risks with foreign political and economic instability.

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, pandemics 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 through possible failure to supply fees or lost business opportunities. The recent COVID-19 pandemic may force us to temporarily close our production facility due to local, state or federal requirements.

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 injectables, 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. As previously noted, on November 26, 2019 FDA issued us a Warning Letter following an inspection of our manufacturing facility at 105 Lincoln Avenue, Buena, New Jersey, that identified several cGMP violations and for which we are continuing diligent remediation activities. The recent COVID-19 pandemic may cause delays in the remediation and re-inspection process.

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. For example, the U.S. Department of Health and Human Services ("DHHS") issued a proposed rule that would remove safe harbor protections for certain rebates. 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 US federal Health Insurance Portability and Accountability Act of 1996, or HIPAA that imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services; similar to the US federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the US federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal health care programs;

- HIPAA, which imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

- state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws,

many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;

- analogous state and foreign laws and regulations relating to health care fraud and abuse, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private 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.

Our business activities may be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws of other countries in which we operate.

We have conducted and have ongoing studies in international locations, and may in the future initiate additional studies in countries other than the United States. Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their governments, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products, if approved, in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

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. Both Congress and President Trump have expressed an intention to repeal or repeal and replace the Affordable Care Act, and as a result certain sections of the Affordable Care Act have not been fully implemented or effectively repealed, and the Fifth Circuit Court of Appeals recently upheld a lower court decision finding the Affordable Care Act's individual mandate to be unconstitutional. The uncertainty around the future of the Affordable Care Act, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. If there are not adequate reimbursement levels, our business and results of operations could be adversely affected. Similarly, there are a number of state and local legislative and regulatory efforts related to drug pricing, including drug price transparency laws that apply to pharmaceutical manufacturers, that may have an impact on our business.

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. The recent COVID-19 pandemic may introduce temporary or permanent healthcare reform measures for which we cannot predict the financial implication of on our business.

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 recent COVID-19 pandemic may create additional risk and delays at our independent third party service providers.

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, 2019 the value of our goodwill and intangible assets net of accumulated amortization was$45.1 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. The recent COVID-19 pandemic may negatively impact North American economies, introduce extreme market volatility and potentially trigger a global 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. The recent COVID-19 coronavirus has negatively impacted the financial markets and may create additional risk for our customers and their ability to pay for our products.

If we are unable to hire additional qualified personnel, our ability to grow or maintain 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. The recent COVID-19 pandemic may cause additional retention and recruitment challenges for the Company.

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. 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, or if we fail to remediate our existing material weaknesses, 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, 2019. We identified a number of material weaknesses in our internal control over financial reporting and concluded that, as of December 31, 2019, 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 2020 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, or if additional material weaknesses are found in our internal controls in the future, 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 recent COVID-19 pandemic could potentially create incremental foreign currency volatility and increase our risks.

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, 2019, we had federal net operating loss carry forwards, or NOLs, of approximately $48.5 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 2018.

The 2017 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).

Thirteen putative class actions have been filed against us and have been consolidated in Multidistrict Litigation in the Eastern District of Pennsylvania regarding the pricing of generic pharmaceuticals, including our antifungal skin cream Econazole Nitrate 1% product. In addition, "Opt-out" antitrust lawsuits have been filed against us by various plaintiffs and all but one has been consolidated into the Multidistrict Litigation. Each of the opt-out complaints names up to forty-seven defendants (including us) and involves allegations regarding the pricing of econazole along with up to 180 other drug products, most of which were not manufactured or sold by us during the period at issue. While we intend to vigorously defend our position in connection with these 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. In May 2016, the EU Parliament adopted the comprehensive General Data Privacy Regulation, or the GDPR to, among other things, impose more stringent data protection requirements for processors and controllers of personal data and provide for greater penalties and fines for noncompliance, including fines in amounts up to €20 million or 4% of total worldwide annual turnover, whichever is higher. The GDPR became fully effective in May 2018. In addition, in 2018, California adopted a new privacy law that went into effect on January 1, 2020, which borrows heavily from the GDPR. Complying with the enhanced obligations imposed by the GDPR and other applicable international and US privacy laws and regulations may result in significant costs to our business and require us to amend certain of our business practices. Further, enforcement actions and investigations by regulatory authorities related to data security incidents and privacy violations continue to increase. The future enactment of more restrictive laws,

rules or regulations and/or future enforcement actions or investigations could have a materially adverse impact on us through increased costs or restrictions on our businesses, and noncompliance could result in regulatory penalties and significant legal liability.

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, 2019, the average daily trading volume of our common stock on the Nasdaq Global Select Market was 411,037 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. The recent COVID-19 pandemic may cause increased risk to our common stock's liquidity and trading price.

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, 2019, and our management concluded that our disclosure controls and procedures were not effective as of December 31, 2019, 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 $0.40 in the fourth quarter of 2019 and a high of $4.46 in the third quarter of 2018. 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;
- speculation about our business in the press or the investment community; and
- global events such as natural disasters, pandemics or acts of terrorism.

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.

Risks Related to our Notes and Senior 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 indentures 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 3.75% Convertible Senior Notes due 2019 (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 May 1, 2023 (the "2023 Notes"). On October 31, 2019, the Company closed its offering of the 2023 Series B Notes in the aggregate principal amount of $34.4 million due May 1, 2023 ("2023 Series B Notes" and together with the 2023 Notes, the "Notes"). As part of the offering, the Company entered into agreements with certain holders of its existing 2023 Notes to exchange $9.0 million of the 2023 Notes for $5.1 million of the 2023 Series B Notes. The gross cash proceeds of approximately $29.3 million from the financing were used to extinguish the Company's existing 2019 Notes in December 2019 and intended to pay amounts owing with respect to other indebtedness and to fund general corporate and working capital requirements. Pursuant to the terms of the indentures governing the Notes, following certain events, holders of the 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. The recent COVID-19 pandemic may create incremental challenges in securing the funds required to pay our Notes.

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, 2019, our total consolidated indebtedness was $214.0 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. The recent COVID-19 pandemic may add to 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 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 Senior Credit Facilities, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control, which is increased as a result of the recent COVID-19 pandemic. 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 into shares of our common stock. 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.

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.

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.

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

On December 13, 2018, we entered into: (i) a First Lien Revolving Credit Agreement, by and among us, as the borrower, certain of our subsidiaries, as guarantors, the lenders from time to time party thereto, and ACF Finco I LP, as administrative agent (the “First Lien Agent”) (as amended on October 31, 2019, the “First Lien Credit Agreement”) and (ii) a Second Lien Credit Agreement, by and among us, as the borrower, certain of our subsidiaries, as guarantors, the lenders from time to time party thereto, and Ares Capital Corporation, as administrative agent (the “Second Lien Agent”) (as amended on February 8, 2019, June 29, 2019 and October 31, 2019, the “Second Lien Credit Agreement” and, together with the First Credit Agreement, the “Senior Credit Facilities”). The Senior Credit Facilities consist of a first lien asset based revolving credit facility of up to $25.0 million ("Revolver") and an aggregate of $80.0 million in original principal amount of second lien term loans consisting of a $50.0 million initial term loan and a $30.0 million delayed draw term loan A (collectively, the “Term Loans”). The Senior Credit Facilities also included a $15.0 million delayed draw term loan b commitment, which remained undrawn and expired on October 31, 2019. As of December 31, 2019, $25.0 million was drawn under the Revolver and $88.5 million of Term Loans were outstanding. As of December 31, 2019, the Revolver was fully drawn. The Revolver bears interest at a fluctuating rate of interest equal to one, two, three or six-month LIBOR plus a margin of 3.75% or a rate based on the prime rate plus a margin of 2.75%. The Revolver matures on the earliest to occur of the June 23, 2024 and the date of that is 91 days prior to the maturity date of each of (x) the 2023 Notes and (y) the 2023 Series B Notes. The Term Loans bear interest at a fluctuating rate of interest equal to one, two, three or six-month LIBOR plus a margin of 8.75% or a rate based on the prime rate plus a margin of 7.75%. The Term Loans mature on the earliest to occur of the June 23, 2024 and the date of that is 181 days prior to the maturity date of each of (x) the 2023 Notes and (y) the 2023 Series B Notes. Interest on the Senior Credit Facilities is payable in cash quarterly in arrears (or more frequently in connection with customary LIBOR interest provisions), provided, that the Company may elect (and has covenanted to the lenders under its First Lien Credit Agreement to) pay interest on the Term Loans in kind until the earlier to occur of the date upon which Company has provided financial statements demonstrating twelve-months of revenue of at least $125,000,000 and (ii) December 28, 2020. As the interest rates applicable to the Senior Facilities are fluctuating, we do have market risk related thereto.

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. The recent COVID-19 pandemic may negatively impact our ability to make scheduled payments or satisfy other obligations pursuant to our Senior Credit Facility.

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 indentures governing the 2023 Notes do not restrict our ability to incur additional indebtedness or require us to maintain financial ratios or specified levels of net worth or liquidity. Thereafter, we and the subsidiary guarantors of the 2023 Series B Notes will continue to be restricted from incurring indebtedness, with

exceptions and baskets as further set forth in the indenture governing the 2023 Series B Notes. All restrictions on the incurrence of indebtedness by us and the subsidiary guarantors in the indenture governing the 2023 Series B Notes will terminate on the first date on which the aggregate outstanding principal balance of the notes is equal to or less than 10% of the original principal balance of the 2023 Series B Notes. 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, thirteen 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 pharmaceuticals, including econazole nitrate. 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 pharmaceuticals from as early as July 1, 2009 until the time the defendants' allegedly unlawful conduct ceased or will cease. The class plaintiffs seek treble damages for alleged overcharges during the alleged period of conspiracy, and certain of the class plaintiffs also seek injunctive relief against the defendants. The 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. On December 19, 2019 certain class plaintiffs filed a further complaint that included additional claims against the Company based on the Company's sales of fluocinolone acetonide. A motion to dismiss this complaint has not yet been filed.

"Opt-out" antitrust lawsuits have additionally been filed against the Company by various plaintiffs, including Humana Inc.; The Kroger Co. et al.; United HealthCare Services, Inc.; Molina Healthcare, Inc.; MSP Recovery Claims, Series LLC; Health Care Service Corp.; and Harris County, Texas. All but one of these complaints have been 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 up to forty-seven defendants (including the Company) and involves allegations regarding the pricing of econazole along with up to 180 other drug products, most of which 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 some 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 remaining opt-out complaints 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. The arbitrator has issued an interim award finding that the Company is not liable to Stayma on two of Stayma's three claims against the Company. The third claim will proceed to a damages phase. The Company has argued that Stayma did not suffer any damages related to this claim and will vigorously pursue complete dismissal of the third claim. In addition, the arbitrator will determine money damages owed by Stayma to the Company relating to Stayma's failure to pay several past due invoices of approximately $1.7 million.

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.

On April 15, 2019 a federal class action was filed the Oklahoma Police Pension Fund and Retirement System against the Company and certain individual defendants in the U.S. District Court, Southern District of New York. The lawsuit was brought on behalf of persons or entities who purchased or otherwise acquired publicly-traded Teligent, Inc. securities from March 7, 2017 through November 6, 2017. The complaint alleges that defendants made false or misleading statements regarding the Company's business, operational, and compliance policies in violation of U.S. securities laws. The plaintiff seeks to recover compensable damages. 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.

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, 2020, there were approximately 342 stockholders of record of our 53,899,495 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

The 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,				
	2019	**2018**	**2017**	**2016**	**2015**
(In thousands, except per share data)					
Revenues	$ 65,896	$ 65,865	$ 60,202	$ 63,012	$ 37,940
Gross profit	23,523	22,385	27,372	34,687	21,315
Operating (loss) income	(8,020)	(15,099)	(11,797)	2,542	(3,192)
Interest and other non-operating income (expense)	(21,339)	(21,219)	(3,479)	(14,240)	9,895
Foreign currency exchange (loss) gain	(1,523)	(3,371)	7,719	(936)	109
Loss before income tax expense	(25,033)	(36,318)	(15,276)	(11,698)	6,703
Income tax (benefit) provision	91	(62)	(85)	287	35
Net (loss) income	(25,124)	(36,256)	(15,191)	(11,985)	6,668
Net (loss) income attributable to common stockholders	(25,124)	(36,256)	(15,191)	(11,985)	6,668
Weighted average shares outstanding:					
Basic	53,839	53,593	53,324	53,078	52,873
Diluted	53,839	53,593	53,324	53,078	67,112
PER SHARE:					
Net (loss) income:					
Basic	(0.47)	(0.68)	(0.28)	(0.23)	0.13
Diluted	(0.47)	(0.68)	(0.28)	(0.23)	(0.07)
BALANCE SHEET DATA:					
Current assets	$ 61,644	$ 48,386	$ 59,131	$ 101,965	$ 115,542
Property, plant and equipment, net	96,349	91,775	68,355	26,215	8,706
Total assets	206,905	190,892	184,585	181,895	183,503
Current liabilities	16,606	32,612	18,696	13,632	9,509
Long-term obligations, less current installments	195,606	139,859	121,136	111,596	107,235
Stockholders' (deficit)/equity	(5,307)	18,421	44,753	56,667	66,759
CASH FLOW DATA:					
Net cash (used in) provided by operating activities	$ (18,419)	$ (13,275)	$ 398	$ (447)	$ (15,459)
Net cash used in investing activities	(8,203)	(25,294)	(40,429)	(20,076)	(53,068)
Net cash provided by (used in) financing activities	30,449	25,333	269	(10)	(3,111)
Net (decrease)/increase in cash, cash equivalents and restricted cash	3,827	(13,236)	(39,762)	(20,533)	(71,638)

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 Operations" section and other sections of this Annual Report on Form 10-K contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about the industry and markets in which the Company operates and on management's beliefs and

assumptions. In addition, other written or oral statements, which constitute forward-looking statements, may be made by or on behalf of the Company. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance, and involve certain risks, uncertainties and assumptions, which are difficult to predict. See “Item 1A: Risk Factors” above. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in such forward-looking statements. The Company undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Company Overview

Strategic Overview

Teligent, Inc. and its subsidiaries (collectively the "Company") is a specialty generic pharmaceutical company. Our mission is to become a leader in the specialty generic pharmaceutical market. Under our own label, we currently market and sell generic topical and generic and branded generic injectable pharmaceutical products in the United States and Canada. In the United States we currently market 38 generic topical pharmaceutical products and four branded generic pharmaceutical products. In Canada we sell 32 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 under our own or a private 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 18 Abbreviated New Drug Applications ("ANDAs") for additional pharmaceutical products filed with the FDA. We have two abbreviated new drug submissions ("ANDSs") on file with Health Canada. In addition, we have 45 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 significant approvals announced in 2019:

On January 2, 2019, we announced approval of an ANDA for Gentamicin Sulfate Ointment USP, 0.1%. This was our thirty-second approval from our internally developed pipeline of topical generic pharmaceutical medicines. We launched this product in the first quarter of 2019.

On January 24, 2019, we announced approval of an ANDA for Clobetasol Propionate Ointment USP, 0.05%. This was our first approval for 2019, and our thirty-third approval from our internally developed pipeline of topical generic pharmaceutical medicines. We launched this product in the first quarter of 2019.

On March 14, 2019, we announced approval of an ANDA for Desonide ointment, 0.05%. This was our second approval of 2019, and our thirty-fourth approval from our internally developed pipeline of topical generic pharmaceutical medicines. We launched this product in the second quarter of 2019.

On March 19, 2019, we announced approval of an ANDA for Fluocinonide Topical Solution USP, 0.05%. This was our third approval of 2019, and our thirty-fifth approval from our internally developed pipeline of topical generic pharmaceutical medicines. We launched this product in the early third quarter of 2019.

On April 4, 2019, we announced approval of an ANDA for Fluocinonide Cream USP, 0.1%. This was our fourth approval of 2019, and our thirty-sixth approval from our internally developed pipeline of topical generic pharmaceutical medicines. We expect to launch this product in the second half of 2021.

On October 18, 2019, we announced approval of an ANDA for Gentamicin Sulfate Cream USP, 0.1% (gentamicin base). This was our fifth approval of 2019, and our thirty-seventh approval from our internally developed pipeline of topical generic pharmaceutical medicines. We launched this product in the fourth quarter of 2019.

Results of Operations

Fiscal year ended December 31, 2019 compared to fiscal year ended December 31, 2018

We had a net loss of $25.1 million, or $0.47 per share, during the year ended December 31, 2019 ("Current Year") compared to net loss of $36.3 million, or $0.68 per share, during the year ended December 31, 2018 ("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:	**2019**	**2018**	**$**	**%**
Product sales, net	$ 64,291	$ 59,591	$ 4,700	8 %
Contract manufacturing sales	1,362	6,047	(4,685)	(77)%
Research and development services and other income	243	227	16	7 %
Total Revenues	$ 65,896	$ 65,865	$ 31	— %

Total revenues were $65.9 million in the Current Year compared to $65.9 million in the Prior Year.

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)	
	2019	2018	$	%
Cost of revenues	$ 42,373	$ 43,480	$ (1,107)	(3)%
Selling, general and administrative	20,785	23,408	(2,623)	(11)%
Product development and research	10,758	14,076	(3,318)	(24)%
Totals costs and expenditures	$ 73,916	$ 80,964	$ (7,048)	(9)%

Total costs and expenditures decreased 9%, or $7.0 million to $73.9 million in the Current Year from $81.0 million in the Prior Year. Cost of revenues decreased as a percentage of total revenue to 64% in the Current Year as compared to 66% in the Prior Year. Cost of revenues decreased $1.1 million in the Current Year mainly due to (i) product mix with lower standard costs, (ii) favorable material revaluations in 2019, (iii) less impact of annual physical inventory and (iv) lower direct salaries and related costs inclusive of stock-based compensation related to options and restricted stock offset by increases to indirect salaries as the Company increased quality staffing in 2019 and depreciation due to the opening of portions of the new facility.

Selling, general and administrative expenses in the Current Year decreased by $2.6 million as compared to the Prior Year. The changes primarily consist of (i) $1.9 million impairment loss in the Prior Year, (ii) $0.7 million decrease in salaries and related costs inclusive of stock-based compensation related to options and restricted stock, (iii) $0.8 million decrease in bad debt expense and (iv) $0.4 million decrease in other costs partially offset by an increase of $0.6 million in professional fees including legal fees and audit fees and an increase of $0.6 million in lease expense.

Product development and research expenses decreased by $3.3 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 invested less in topical R&D for 2019. This was mainly due to (i) $0.4 million decrease in clinical studies, (ii) $1.1 million decrease in salaries and related costs inclusive of stock based compensation related to options and restricted stock, (iii) $0.8 million decrease in exhibit and pilot batch costs, (iv) $0.8 million decrease in GDUFA and associated fees and (v) $0.2 million decrease in contract research.

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

	Year Ended December 31,		Increase/(Decrease)	
	2019	2018	$	%
Interest and other expense, net	$ (21,154)	$ (12,298)	$ 8,856	72 %
Foreign exchange loss	$ (1,523)	$ (3,371)	(1,848)	55 %
Loss on debt restructuring	$ (920)	$ —	920	— %
Debt partial extinguishment of 2019 Notes	$ (185)	$ (4,235)	(4,050)	100 %
Change in the fair value of derivative liability	$ 6,769	$ —	(6,769)	— %
Debt extinguishment of prior term loan	$ —	$ (1,315)	(1,315)	100 %

Interest and other expense, net increased in the Current Year primarily as a result of a decrease in capitalized interest of $4.6 million from Prior Year pertaining to the Buena Facility and an increase in interest expense of $4.3 million related to the current debt structure.

Foreign exchange loss of $1.5 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.

Debt partial extinguishment on the 2019 Notes was $0.2 million in the Current Year compared to $4.2 million in the Prior Year. Debt extinguishment of the Prior Term Loan was zero in the Current Year compared to $1.3 million in the Prior Year.

The gain on the change in fair value of derivative of the 2023 Series B Notes was $6.8 million in the Current Year.

Loss on debt restructuring in the Current Year was $0.9 million.

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

	Year Ended December 31,		Increase/(Decrease)	
	2019	2018	$	%
Net loss attributable to common stockholders	$ (25,124)	$ (36,256)	$ (11,132)	31 %
Basic and diluted loss per share	$ (0.47)	$ (0.68)	$ (0.21)	31 %

Net loss for the Current Year was $25.1 million as compared to net loss of $36.3 million for the Prior Year. The decrease is primarily due to decrease i) in costs and expenses of $7.0 million, ii) in foreign exchange loss of $1.8 million, (iii) debt extinguishment losses of $5.4 million and iv) derivative liability of $6.8 million, partially offset by an increase in interest and other expenses of $8.9 million and loss on debt restructuring of $0.9 million in the Current Year as discussed above.

Liquidity and Capital Resources

The Company has incurred significant losses and generated negative cash flows from operations in recent years and expects to continue to incur losses and generate negative cash flow for the foreseeable future. As a result, the Company had an accumulated deficit of $121.5 million, total principal amount of outstanding borrowings of $214.0 million, and limited capital resources to fund ongoing operations at December 31, 2019. These capital resources were comprised of cash and equivalents of $15.5 million at December 31, 2019 and the generation of cash inflows from working capital. We had working capital of $45.0 million at December 31, 2019. The Company's available capital resources may not be sufficient for it to continue to meet its obligations as they become due over the next twelve months if we cannot improve our operating results or increase our operating cash inflows. In the event these capital resources are not sufficient, we may need to raise additional capital through the sale of equity or debt securities, enter into strategic business collaboration agreements with other companies, seek other funding facilities, or sell assets. However, the Company cannot provide assurances that additional capital will be available on acceptable terms or at all. Moreover, if the Company is unable to meet its obligations when they become due over the next twelve months through our available capital resources, or obtain new sources of capital when needed, the Company may have to delay expenditures, reduce the scope of our manufacturing operations, reduce or eliminate one or more of our development programs, make significant changes to our operating plan, or cease operations.

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 substantially completed in October of 2018, additional investment was made in order to prepare the facility and our employees for a prior approval inspection from the FDA for our injectable line. In addition, we expect to continue to incur significant expenditures for the development of new products in our pipeline, and the manufacturing, 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, 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 $3.8 million increase in our cash during the twelve months ended December 31, 2019 was largely due to the issuance of the 2023 Series B Notes issued by the Company in the fourth quarter of 2019, offset by the settlement of the 2019 Notes also in the fourth quarter of 2019. In addition, we had an accumulated deficit of $121.5 million as of December 31, 2019 and incurred a $25.1 million net loss and used $18.4 million in net cash from operating activities during the twelve months ended December 31, 2019.

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 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 $4.45 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 issuance costs of $1.6 million upon the 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. The third quarter 2018 Form 10-Q was filed on December 12, 2018, after our extended deadline. As a result, our access to offer up to $50.0 million of the identified securities was suspended for twelve months. On December 12, 2019 the Form S-3 registration was once again made available to the Company.

On December 13, 2018, we entered into the Senior Credit Facilities, consisting of the Revolver and Term Loans. The Senior Credit Facilities also included a $15.0 million delayed draw term loan B commitment, which remained undrawn and expired on October 31, 2019. As of December 31, 2019, $25.0 million was drawn under the Revolver and $88.5 million of Term Loans were outstanding. The Initial Term Loan matures on the earlier to occur of (a) prior to maturity of the 2023 Notes and (b) June 13, 2024. We extended commitments related to undrawn amounts of the Delayed Draw Term Loan A from June 30, 2019 to December 13, 2019, pursuant to an amendment we entered with the Second Lien Agent on July 18, 2019. The extended Delayed Draw Term Loan A was subsequently drawn down by us in December 2019. Drawn amounts under the Delayed Draw Term Loans mature at the same time as the Initial Term Loan. The Term Loans mature on the earliest to occur of the June 23, 2024 and the date of that is 181 days prior to the maturity date of each of (x) the 2023 Notes and (y) the 2023 Series B Notes. The Revolver matures on the earliest to occur of the June 23, 2024 and the date of that is 91 days prior to the maturity date of each of (x) the 2023 Notes and (y) the 2023 Series B Notes. 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 the Collateral. All of our debt is subordinated to the Senior Credit Facilities. The liens securing the Term Loans are subordinated to the liens securing the Revolver. The Senior Credit Facilities had 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 which were superseded by the amendments noted below. The financial covenants consisted 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 beginning of 2019, the Company used a total of $2.7 million of proceeds from the Senior Credit Facilities to repurchase a portion of the remaining 2019 Notes. The repurchase of the 2019 Notes is considered a debt extinguishment under ASC 470-50. The 2019 Notes are accounted for under cash conversion guidance ASC 470-20, which requires the Company 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. In accordance with the guidance above, the Company allocated a portion of the $2.7 million to the extinguishment of the liability component equal to the fair value of that component immediately before extinguishment and recognized a $0.2 million extinguishment loss in the Consolidated Statement of Operations to measure the difference between (i) the fair value of the liability component and (ii) the net carrying value amount of the liability component (which is already net of any unamortized debt issuance costs). The reduction of Additional Paid in Capital in connection with this extinguishment was immaterial. The Company settled the remaining 2019 Notes of $13.0 million in principal upon its maturity in December 2019.

The Initial Term Loan of $50.0 million and $15.0 million of the Revolver were drawn by the Company on December 13, 2018. On December 21, 2018, the Company drew $20.0 million of the Delayed Draw Term Loan A. In January 2019, the Company drew $5.0 million and subsequently the remaining $5.0 million under the Revolver were drawn down by the Company in April 2019. On September 18, 2019, pursuant to the Protective Advance clause in the Company’s First Lien Credit Agreement with Ares Capital, the Company borrowed an incremental $2.5 million from its existing revolving credit facility. Consistent with the terms of the revolving credit facility, Protective Advances are secured by the Administrative Agent’s liens, constitute Obligations pursuant to the First Lien Credit Agreement, and bear interest at the rate applicable to the outstanding revolving credit facility balances, however, the Protective Advance is repayable on demand. The liability was subsequently paid off in November 2019 along with repayment fee of $0.1 million. The Company drew down the remaining $10 million under its

borrowing capacity of Delayed Draw Term Loan A before its expiry in December of 2019.The $15 million Delayed Draw Term Loan B expired upon the issuance of the Series B Notes, prior to the Company drawing down any monies.

The Term Loans are governed by the Second Lien Credit Agreement. The 2023 Term Loans include a 24-month paid-in-kind interest option available to the Company should it choose to defer cash payments in order to maintain the liquidity needed to continue launching new products, and preparing for an FDA prior approval inspection of its new injectable manufacturing facility. The Company has elected the paid-in-kind interest option and increased the principal balance of 2023 Term Loans by$8.5 million for the year ended December 31, 2019.

On October 31, 2019, the Company closed its Series B Notes offering in the aggregate principal amount of $34.4 million. The Series B Notes will mature in May 2023 and are convertible at the option of the holder at any time prior to maturity at an initial conversion price of $0.72 per share, subject to adjustment under certain circumstances. The Series B Notes and any shares of common stock issuable upon conversion of the Series B Notes (the “Conversion Shares”) have not been registered under the Securities Act of 1933, as amended (the “Securities Act”), or any state or other jurisdiction’s securities laws, and the New 2023 Notes and the Conversion Shares may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Securities Act and applicable state or other jurisdictions’ securities laws. The Company does not intend to file a registration statement for the resale of the Series B Notes or any Conversion Shares.

As part of the offering, the Company entered into agreements with certain holders of its existing 2023 Notes to exchange $9.0 million of the 2023 Series A Unsecured Convertible Notes for $5.1 million of the Series B Senior Unsecured Convertible Notes. The gross cash proceeds of approximately $29.3 million from the financing were used to extinguish the Company’s existing 2019 Notes in December 2019 and intended to pay amounts owing with respect to other indebtedness and to fund general corporate and working capital requirements. The Series B Notes bear interest at a rate of 7.00% per annum if paid in cash, semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2020. The Company also has an option, and has agreed with its senior lender, to PIK the interest at 8.00% per annum, to defer cash payments. The net proceeds from the financing were $26.9 million after deducting a total of $2.3 million of the initial purchasers’ discounts and professional fees associated with the transaction.

Under ASC 470-60, Troubled Debt Restructurings by Debtors, the exchange of the $9.0 million of the Series A 2023 notes for the $5.1 million of the Series B Notes represents a troubled debt restructuring ("TDR"). The TDR did not result in a gain recognition. As a result, a new effective interest rate was established based on the $7.2 million carrying value of the original debt, net of the $2.0 million fair value of the embedded derivative liability related to the new debt issued in the TDR and $0.2 million issuance costs, getting accreted to $6.8 million representing the total amount of the future undiscounted cash flows related to the $5.1 million of the Series B Notes.

In accordance with ASC 815-15, Derivatives and hedging, Embedded Derivatives, the embedded conversion option should be bifurcated and separately accounted for as a derivative instrument, because the Company did not have enough authorized shares available to share-settle the conversion option. Such derivative instruments should be initially and subsequently measured at fair value, with changes in fair value recognized in earnings (see Note 7). The derivative liability recorded at the issuance date was $13.5 million, including the $2.0 million above accounted for in the TDR, which was subsequently remeasured to $6.8 million as of December 31, 2019, with $6.8 million recognized as a gain on change in fair value of derivative in the Company's statement of operations. Further, the $0.9 million of allocated issuance costs associated with the bifurcated conversion features embedded in the notes was recognized as a loss on debt restructuring in the Company’s statement of operations for the year ended December 31, 2019. In accordance with ASC 470-20, the initial carrying amount of the liability component of the Series B Notes, excluding the $5.1 million portion above is accounted for as a TDR, upon issuance is the residual amount between total proceeds from the transaction and the derivative liability net of allocated issuance costs. The $1.4 million debt issuance costs attributable to the liability component were recorded as a direct deduction from the liability component of the Series B Notes and are being amortized to interest expense using the effective interest method through the maturity date. The discount from the par amount of the Notes will be accreted to par utilizing the effective-interest rate method over the term of the Notes from the issuance date through May 2023. The effective interest rate of the 2023 Notes, inclusive of the debt discount and issuance costs is 27.4%.

On April 6, 2020, the Company entered (i) Amendment No. 2 of the Revolver and Amendment No. 4 of the Term Loans, effective as of December 31, 2019. The amendments collectively among other things, (i) increase the interest rates, (ii) reset certain prepayment premiums and modify the terms of certain mandatory prepayments and (iii) modify certain financial covenant levels inclusive of the disposition of prior covenants as of and for the period ended December 31, 2019. These financial covenants include a trailing twelve months (“TTM”) Minimum Revenue covenant that is required to be met each quarterly period from March 31, 2020 through December 31, 2020, a TTM Minimum Adjusted EBITDA that is required to be met each quarterly period from March 31, 2021 through maturity, and a minimum liquidity covenant tested at all times through the term of the agreement. These amendments supersede the financial covenants included in the original and amended

agreements. Pursuant to the amended Ares Credit Agreements, in the event the Company is unable to comply with these covenants, or obtain a waiver from its lenders, the lender shall have the right, but not the obligation, to permanently reduce the commitment in whole or in part or to declare all or any portion of the outstanding balance due and payable. Furthermore, in the event that outstanding balances under the Ares Credit agreements are declared due and payable by the lender, the lenders of the 2023 Series A and Series B Unsecured Convertible Notes shall have the right, but not the obligation, to declare all of the outstanding balance due and payable as well. The Company does not currently have available liquidity to repay these outstanding borrowings in the event of a default. If the Company is unable to raise additional capital to meet these obligations, the Company may have to seek other strategic alternatives, including ceasing its operations.

In June 2019, the Company received a de-listing notice from the NASDAQ due to its share price being below $1.00 for 30 consecutive trading days. The notice specified that the Company's share price must trade above $1.00 per share for ten consecutive trading days prior to December 2, 2019 in order to prevent its common stock from being de-listed. For the 180 days preceding December 2, 2019 the Company's share price remained below $1.00. The Company requested a second 180-day extension. NASDAQ denied its request and the Company chose to file for an appeal. The Company was granted a hearing date for the end of January 2020. Subsequent to the appeal hearing, NASDAQ set a deadline of April 17, 2020 for the Company to regain compliance with NASDAQ's continuing listing requirements. In early March 2020 the COVID-19 global pandemic triggered a significant decline in global capital markets, including NASDAQ. In light of this significant decline, the Company requested NASDAQ to reconsider the April 17, 2020 deadline. NASDAQ agreed to the Company's request and set a new deadline to regain compliance by June 1, 2020. In January 2020, the Company's Board of Directors and shareholders approved a reverse stock split in the range of any whole number between five (5) and ten (10) to one (1). While the Company believes that the reverse stock split will ultimately increase its share price above $1.00 for the required ten consecutive trading days, it can provide no assurances that its shares will trade above $1.00 per share for the required time period. A de-listing from the NASDAQ would be a "Fundamental Change" under the Company's 2023 Series A and Series B Unsecured Convertible Notes which triggers a right by the holders to require the Company repurchase the Convertible Notes. In such an event, the Company would need to seek financing to repurchase the Convertible Notes and there is no guarantee that such financing would be available or on terms acceptable to the Company. If noteholders demanded a repurchase of the notes and the Company could not finance the repurchase, it would be in default under the Indentures governing the Convertible Notes, and in that event the lenders of the Ares Credit agreements would have the right, but not the obligation, to declare all of the outstanding balance under those agreements due and payable as well. Therefore, in the event of the Company's shares are de-listed from the NASDAQ, the Company would likely have to seek some combination of waivers from its lenders and noteholders and seek new capital through the sale of equity or debt securities. If the Company is unable to obtain such waivers or raise new capital to meet these obligations if they become due, it may have to seek other strategic alternatives, including ceasing operations.

The negative financial conditions described above raise substantial doubt about our ability to continue as a going concern as of December 31, 2019.

Operating Activities

Our operating activities used $18.4 million of cash during the year ended December 31, 2019 compared to $13.3 million during the year ended December 31, 2018. The cash used for the year ended December 31, 2019 was mostly due to an increase in accounts receivable of $3.7 million and inventories of $6.1 million, and a reduction in deferred income of $2.4 million, in addition to $5.6 million of interest paid on our Notes, Revolver, and Term Loans. 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.

Investing Activities

Our investing activities used $8.2 million during the year ended December 31, 2019 compared to $25.3 million for the year ended December 31, 2018. The funds used for the year ended December 31, 2019 included $8.2 million in capital expenditure, the majority of which were for the continued facility expansion in Buena, NJ. The funds used for the year ended December 31, 2018 included $25.3 million in capital expenditures, the majority of which were also for the facility expansion in Buena.

Financing Activities

Our financing activities provided $30.4 million of cash during the year ended December 31, 2019 compared to $25.3 million of cash provided by in the year ended December 31, 2018. The cash provided during the year ended December 31, 2019 consisted of proceeds from the 2023 Series B Notes net of issuance costs of $26.9 million as well as net borrowing from the Company's Senior Credit Facility of $19.2 million, offset by the settlement of our 2019 Notes of $15.7 million. The cash provided during

the year ended December 31, 2018 consisted of proceeds from the Prior Term Loan which was later replaced by the Senior Credit Facilities with Ares Capital Management.

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, 2019 are presented below. Outstanding debt and interest obligation are 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.

		Obligations 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	$ —	$ —	$ —	$ —	$ —
Long term debt obligations	213,959	—	25,000	188,959	—
Interest on debt obligations	59,915	17,277	36,525	6,113	—
Operating Lease	3,423	635	1,160	785	843
Total	**$ 277,297**	**$ 17,912**	**$ 62,685**	**$ 195,857**	**$ 843**

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, 2019 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, 2019 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.

As of December 31, 2019, based on level 2 inputs, the fair value of our 2023 Notes was approximately$23.0 million compared to their carrying value of $53.1 million and the fair value of our 2023 Series B Notes was approximately $28.9 million including the derivative liability of $6.8 million as mentioned below.

As of December 31, 2019, based on level 3 inputs, the fair value of the derivative liability associated with our 2023 Series B Notes was $6.8 million. (Note 7).

Accounts Receivable and Allowance for Doubtful Accounts

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.

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.

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 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. The Company reviews the percentage of products sold through these programs by reviewing chargeback data and applies the appropriate percentages to calculate the rebate accrual. Rebates invoices and/or payments are received monthly, quarterly or annually and reviewed against the accruals. Other items that could be included in accrued rebates represent 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 the valuation of the derivative liability associated with certain Notes, sales returns and allowances, allowances for excess and obsolete inventories, allowances for doubtful accounts, provisions for income taxes and related valuation allowances, stock based compensation, the assessment for the impairment of long-lived assets (including intangibles, goodwill and property, plant and equipment), property, plant and equipment and legal accruals. The Company bases its estimates and assumptions on historical experience, known or expected trends and various other assumptions that it believes to be reasonable. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates.

Accounting Pronouncements

See Note 2 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, 2019, our principal debt obligations consisted of our 2023 Notes, our 2023 Series B Notes and our Senior Credit Facilities.

On April 27, 2018, we entered into separate exchange agreements with certain holders of our then outstanding 2019 Notes. The agreements gave the holders the right to exchange an aggregate of $75.1 million of the 2019 Notes for $75.1 million of 2023 Notes. The 2023 Notes bear a fixed interest rate of 4.75% per year, payable semi-annually in cash with the principal payable in May 2023. At the option of the holders, the 2023 Notes are convertible into shares of the Company's common stock, cash or a combination thereof at an initial conversion price per share of $4.45, subject to adjustment in certain circumstances. In addition, holders will be entitled to receive additional shares of common stock for a potential increase in the conversion rate under a make-whole provision in some circumstances. As the interest rate under the 2023 Notes is fixed, we have no market risk related thereto.

On October 28, 2019, we completed the sale of $29.3 million aggregate principal amount of our 2023 Series B Notes for cash and we issued an additional $5.1 million aggregate principal amount of the 2023 Series B Notes in exchange for an aggregate principal amount of $9.0 million of the 2023 Notes. Interest on the outstanding principal of the 2023 Series B Notes accrues at either (x) a fixed rate of 7% if the Company elects to pay interest in cash or (y) 8% if the Company elects to pay interest in kind. In any case, interest is due and payable (either in cash or in kind, as elected by the Company) semi-annually every May 1 and November 1 (commencing on May 1, 2020) until the 2023 Series B Notes mature on May 1, 2023. Holders of the 2023 Series B Notes are entitled to convert principal and accrued, unpaid interest on the 2023 Series B Notes into, at the Company's election, cash, shares of Common Stock, or a combination thereof, at an initial conversion price per share of Common Stock equal to $0.72, subject to adjustment under certain circumstances. The Company has covenanted to its lenders under the Senior Credit Facilities to not elect to pay interest in cash for so long as it has the option to do so. As the interest rate under 2023 Series B Notes is fixed, we have no market risk related thereto.

On December 13, 2018, we entered into the Senior Credit Facilities, consisting of the Revolver and Term Loans. The Senior Credit Facilities also included a $15.0 delayed draw term loan b commitment, which remained undrawn and expired on October 31, 2019. As of December 31, 2019, $25.0 million was drawn under the Revolver and $88.5 million of Term Loans were outstanding. As of December 31, 2019, the Revolver was fully drawn. The Revolver bears interest at a fluctuating rate of interest equal to one, two, three or six-month LIBOR plus a margin of 3.75% or a rate based on the prime rate plus a margin of 2.75%. The Revolver matures on the earliest to occur of the June 23, 2024 and the date of that is 91 days prior to the maturity date of each of (x) the 2023 Notes and (y) the 2023 Series B Notes. The Term Loans bear interest at a fluctuating rate of interest equal to one, two, three or six-month LIBOR plus a margin of 8.75% or a rate based on the prime rate plus a margin of 7.75%. The Term Loans mature on the earliest to occur of the June 23, 2024 and the date of that is 181 days prior to the maturity date of each of (x) the 2023 Notes and (y) the 2023 Series B Notes. Interest on the Senior Credit Facilities is payable in cash quarterly in arrears (or more frequently in connection with customary LIBOR interest provisions), provided, that the Company may elect (and has covenanted to the lenders under its First Lien Credit Agreement to) pay interest on the Term Loans in kind until the earlier to occur of the date upon which Company has provided financial statements demonstrating twelve-months of revenue of at least $125,000,000 and (ii) December 28, 2020. As the interest rates applicable to the Senior Facilities are fluctuating, we do have market risk related thereto.

On April 6, 2020, the Company entered (i) Amendment No. 2 of the Revolver and Amendment No. 4 of the Term Loans, effective as of December 31, 2019. The amendments collectively among other things, (i) increase the interest rates, (ii) reset certain prepayment premiums and modify the terms of certain mandatory prepayments and (iii) modify certain financial covenant levels inclusive of the disposition of prior covenants as of and for the period ended December 31, 2019.

The associated increase in interest rates are effective as of the Amendment Closing Date. The Revolver bears interest at a fluctuating rate of interest equal to the one, two, three or six-month LIBOR plus a margin of 5.50% or a rate based on the prime rate plus a margin of 4.50%, with a LIBOR floor of 1.5%. The Term Loans bear interest at a fluctuating rate of interest equal to the one, two, three or six-month LIBOR plus a margin of 13.0% or a rate based on the prime rate plus a margin of 12.0%, with a LIBOR floor of 1.5%. Interest on the Senior Credit Facilities is payable in cash quarterly in arrears (or more frequently in connection with customary LIBOR interest provisions), provided, that the Company may elect (and has covenanted to the lenders under its Senior Credit Facilities and subsequent amendments thereto) to pay interest on the Term Loans in kind through December 13, 2021 but only if the following occurs: (1) the Company receives a "warning letter close-out letter" from the Federal Drug Administration in response to corrective actions taken by the Company since receipt of the warning letter in November 2019 and (2) the Company receives a written recommendation from the Federal Drug Administration setting forth its approval decision in respect of the pre-approval inspection for commercial production on the newly installed injectable line at the Company's New Jersey facility. If only one of those items occurs by December 13, 2020, then the Company may still elect

to pay interest in kind during 2021, but only from the time the second condition has been satisfied until December 13, 2021. Thereafter, a portion of interest on the loans accruing at a rate of 4.25% per annum may continue to be paid in kind.

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, 2019, based on level 2 inputs, the fair value of our 2023 Notes was approximately $23.0 million compared to their carrying value of $53.1 million and the fair value of our 2023 Series B Notes was approximately $28.9 million including the derivative liability of $6.8 million.

For a description of the fair value hierarchy and the Company's fair value methodologies, see Note 2 "Summary of Significant Accounting Policies."

As of December 31, 2019, 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, 2019, 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, 2019 (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, 2019. 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
- 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 deficiency 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 for the completeness and accuracy of source data in the calculation of certain gross-to-net revenue reserves and allowances;

- Inadequate segregation of duties.

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 obtaining, generating, and using relevant quality information to support the function 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:

- As new controls were implemented throughout the year, testing procedures were delayed, which resulted in delayed and limited communication of control failures to process owners.

- Failure to effectively communicate relevant information and internal control deficiencies to our Audit Committee for appropriate oversight, monitoring and enforcement of corrective action.

As the Company is now classified as a smaller reporting company, Deloitte & Touche LLP, our independent registered public accounting firm, has not audited the effectiveness of our internal control over financial reporting as of December 31, 2019.

Changes in Internal Control Over Financial Reporting

There were changes made during the year ended December 31, 2019 in our internal control over financial reporting that have affected, or are reasonably likely to affect, our internal control over financial reporting. These changes, however, were

not all in place for an adequate period of time for management to appropriately assess the operating effectiveness of these controls.

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 2020 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 have 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 evaluate and correct segregation of duties concerns where possible: however due to the limited size of the organization, inclusive of the finance and IT departments, management may not economically be able to correct certain segregation of duty issues . We 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 when budgets permit. 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 to implement 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 have enhanced corporate oversight of process-level controls and structures to ensure that there is appropriate assignment of authority, responsibility, and accountability to further the remediating of 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 continue to monitor internal audit, finance, accounting, and information technology staffing levels.

• We are also developing effective communication plans relating to, among other things, the 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

None.

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 and “Code of Conduct and Ethics” in the Company’s Proxy Statement for the 2020 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 and “Management and Corporate Governance in the Company’s Proxy Statement for the 2020 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 2020 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 2020 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 2020 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” 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).
(4.3)	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)
(4.4)	Indenture, dated as of October 31, 2019, by and among the Company, certain subsidiary guarantors named therein, and Wilmington Trust, National Association, as Trustee (incorporated by reference to Exhibit 4.1 to the Company's Report on Form 8-K, filed October 31, 2019).
(4.5)	Form of Note (incorporated by reference to Exhibit 4.2 to the Company's Report on Form 8-K, filed October 31, 2019)
(4.6)*	Description of Capital Stock (filed herewith).
(4.7)	Form of Warrant, dated as of April 6, 2020, by and among the Company and the lenders party thereto (incorporated by reference to Exhibit 4.1 to the Company's Report on Form 8-K filed April 8, 2020).
(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 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).
(10.10)+	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).

(10.11)	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).
(10.12)	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 10.2 to the Company's Report on Form 8-K, filed October 1, 2014).
(10.13)+	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).
(10.14)	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).
(10.15)	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).
(10.16)	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).
(10.17)	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).
(10.18)	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).
(10.19)+	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).
(10.20)	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).
(10.21)	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).
(10.22)	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).
(10.23)	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).

(10.24)	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).
(10.25)	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).
(10.26)	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).
(10.27)	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).
(10.28)	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).
(10.29)#	Teligent, Inc. 2016 Equity Incentive Plan, as amended Equity Incentive Plan, as amended (incorporated by reference to Exhibit (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q/A Amendment No. 1 for the quarter ended June 30, 2018 filed December 12, 2018).
(10.30)#	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).
(10.31)#	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).
(10.32)#	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).
(10.33)#	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).
(10.34)#	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).
(10.35)#	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).
(10.36)#	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).
(10.38)#	Employment Agreement dated January 2, 2018 between the Company and Damian Finio (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed January 26, 2018).
(10.39)*	Amendment No. 1 dated February 8, 2018 to Second Lien Credit Agreement dated December 31, 2018 by and among the Company, certain subsidiaries, the lenders from time to time party thereto, and Ares Capital Corporation, as Administrative Agent (filed herewith).

(10.40)*	Amendment No. 2 dated July 18, 2019 to Second Lien Credit Agreement dated December 31, 2018 by and among the Company, certain subsidiaries, the lenders from time to time party thereto, and Ares Capital Corporation, as Administrative Agent (filed herewith).
(10.41)	Form of Purchase Agreement, dated as of October 28, 2019, between the Company and the purchaser party thereto (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed October 31, 2019).
(10.42)	Form of Exchange Agreement, dated as of October 28, 2019, between the Company and the exchanging noteholder party thereto (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K filed October 31, 2019).
(10.43)	Consent and Amendment No. 1 to First Lien Credit Agreement, dated as of October 31, 2019, by and among the Company, certain subsidiaries thereto, the lenders party thereto, and ACF Finco I LP, as Administrative Agent (incorporated by reference to Exhibit 10.3 to the Company's Report on Form 8-K filed October 31, 2019).
(10.44)	Consent and Amendment No. 3 to Second Lien Credit Agreement, dated as of October 31, 2019, by and among the Company, its subsidiaries signatory thereto, the lenders party thereto, and Ares Capital Corporation, as Administrative Agent (incorporated by reference to Exhibit 10.4 to the Company's Report on Form 8-K filed October 31, 2019).
(10.45)	Teligent, Inc. Change in Control Severance Policy (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed on January 15, 2020).
(10.46)*#	Separation Agreement between the Company and Jason Grenfell-Gardner dated February 5, 2020 (filed herewith).
(10.47)#	Employment Agreement dated February 4, 2020 between the Company and Tim Sawyer (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed February 5, 2020).
(10.48)	Amendment No. 2 to First Lien Credit Agreement, dated as of April 6, 2020, by and among the Company, its subsidiaries signatory thereto, the lenders party thereto, and ACF Finco I LP, as Administrative Agent (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed April 8, 2020).
(10.49)	Amendment No. 4 to Second Lien Credit Agreement, dated as of April 6, 2020 by and among the Company, its subsidiaries signatory thereto, the lenders party thereto, and Ares Capital Corporation, as Administrative Agent (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K filed April 8, 2020).
(21)*	List of Subsidiaries (filed herewith).
(23.1)*	Consent of Deloitte & Touche LLP (filed herewith).
(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 (filed herewith).
(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 (filed herewith).
(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 (filed herewith).
(101)*	The following financial information from this Annual Report on Form 10-K for the year ended December 31, 2019, 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/ Timothy B. Sawyer
Timothy B. Sawyer
President and Chief Executive Officer

Date: April 13, 2020

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/ Timothy B. Sawyer Timothy B. Sawyer	Director, President and Chief Executive Officer (Principal Executive Officer)	April 13, 2020
/s/ Damian Finio Damian Finio	Chief Financial Officer (Principal Financial Officer, Principal Accounting Officer)	April 13, 2020
/s/ Steven Koehler Steven Koehler	Director	April 13, 2020
/s/ James Gale James Gale	Director	April 13, 2020
/s/ Bhaskar Chaudhuri Bhaskar Chaudhuri	Director	April 13, 2020
/s/ John Celentano John Celentano	Director	April 13, 2020
/s/ Carole Ben-Maimon Carole Ben-Maimon	Director	April 13, 2020
/s/ Thomas Sabatino Thomas Sabatino	Director	April 13, 2020

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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 sheets of Teligent, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has stated that the uncertainty they anticipate in maintaining sufficient liquidity to fund ongoing operations raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has adopted Accounting Standards Update 842, *Leases*, using the optional transition method, on January 1, 2019.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the 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 financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Deloitte & Touche LLP

Parsippany, New Jersey

April 13, 2020

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

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

	12/31/2019	12/31/2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,508	$ 9,705
Restricted cash	206	2,892
Accounts receivable, net of allowance for doubtful accounts of $2,208 and $2,636, as of December 31, 2019 and December 31, 2018, respectively	20,374	16,120
Inventories	23,031	16,296
Prepaid expenses and other receivables	2,525	3,373
Total current assets	61,644	48,386
Property, plant and equipment, net	96,349	91,775
Intangible assets, net	44,645	48,375
Goodwill	491	470
Other	3,776	1,886
Total assets	$ 206,905	$ 190,892
LIABILITIES AND STOCKHOLDERS' (DEFICIT)/EQUITY		
Current liabilities:		
Accounts payable	$ 6,875	$ 5,933
Accrued expenses	9,285	9,842
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
Capital lease obligation, current	446	—
Total current liabilities	16,606	32,612
Convertible 4.75% Senior Notes, net of debt discount and debt issuance costs (face of $66,090 and $75,090 as of December 31, 2019 and December 31, 2018, respectively)	53,093	56,909
Revolver (face of $25,000 and $15,000 as of December 31, 2019 and December 31, 2018, respectively)	25,000	15,000
Series B Senior Convertible Notes, net of debt discount and debt issuance costs (face of $34,405 as of December 31, 2019)	21,824	—
2023 Term Loan, net of debt issuance costs (face of $88,464 and $70,000 as of December 31, 2019 and December 31, 2018, respectively)	86,452	67,662
Derivative liability	6,776	—
Deferred tax liability	205	215
Other long term liabilities	2,256	73
Total liabilities	212,212	172,471
Commitments and Contingencies		
Stockholders' (deficit)/equity:		
Common stock, $0.01 par value, 100,000,000 shares authorized; 53,850,427 and 53,774,221 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	558	557
Additional paid-in capital	117,967	116,864
Accumulated deficit	(121,474)	(96,350)
Accumulated other comprehensive loss, net of taxes	(2,358)	(2,650)
Total stockholders' (deficit)/equity	(5,307)	18,421
Total liabilities and stockholders' (deficit)/equity	$ 206,905	$ 190,892

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

TELIGENT, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
For the years ended December 31, 2019 and 2018
(in thousands, except shares and per share information)

	2019	2018
Revenue, net	$ 65,896	$ 65,865
Costs and Expenses:		
Cost of revenues	42,373	43,480
Selling, general and administrative expenses	20,785	23,408
Product development and research expenses	10,758	14,076
Total costs and expenses	73,916	80,964
Operating loss	(8,020)	(15,099)
Other Expense:		
Foreign currency exchange loss	(1,523)	(3,371)
Debt partial extinguishment of 2019 Notes	(185)	(4,235)
Debt extinguishment of Prior Term Loan	—	(1,315)
Interest and other expense, net	(21,154)	(12,298)
Change in the fair value of derivative liability	6,769	—
Loss on debt restructuring	(920)	—
Loss before income tax expense	(25,033)	(36,318)
Income tax expense / (benefit)	91	(62)
Net loss attributable to common stockholders	$ (25,124)	$ (36,256)
Basic and diluted loss per share	$ (0.47)	$ (0.68)
Weighted average shares of common stock outstanding:		
Basic and diluted	53,839,139	53,592,930

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, 2019 and 2018
(in thousands)

	2019	2018
Net loss	$ (25,124)	$ (36,256)
Other comprehensive loss, net of tax		
Foreign currency translation adjustment	292	(631)
Other comprehensive loss	292	(631)
Comprehensive loss	$ (24,832)	$ (36,887)

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, 2019 and 2018
(in thousands)

	2019	2018
Cash flows from operating activities:		
Net loss	$ (25,124)	$ (36,256)
Reconciliation of net loss to net cash provided by (used in) operating activities:		
Depreciation of fixed assets	3,688	2,579
Gain on sale of assets	—	(20)
Provision for write down of inventory	(459)	1,363
Provision for bad debt	(428)	452
Issuance of stock to consultant	—	102
Stock based compensation	1,076	1,970
Amortization of debt costs and debt discount	6,514	9,226
Amortization of intangibles	3,008	3,096
Non cash lease expense	408	—
Deferred income taxes	(22)	73
Foreign currency exchange loss (gain)	1,523	3,371
Partial extinguishment of 3.75% senior notes	185	4,235
Non cash interest expense	8,464	—
Extinguishment of prior term loan	—	1,315
Loss on impairment of intangible assets	—	1,924
Loss on debt restructuring	920	—
Change in the fair value of derivative liability	(6,769)	—
Changes in operating assets and liabilities:		
Accounts receivable	(3,655)	(4,047)
Inventories	(6,145)	(1,877)
Prepaid expenses and other current receivables	803	224
Other assets	12	(26)
Accounts payable and accrued expenses	377	(3,405)
Operating liabilities	(369)	—
Deferred income	(2,426)	2,426
Net cash used in operating activities	(18,419)	(13,275)
Cash flows from investing activities:		
Capital expenditures	(8,203)	(25,332)
Disposal of fixed assets	—	38
Net cash used in investing activities	(8,203)	(25,294)
Cash flows from financing activities:		
Proceeds from prior term loan	—	25,000
Proceeds from 2023 term loan	10,000	70,000
Proceeds from 2023 Series B senior notes	17,750	—
Proceeds from 2023 Series B bifurcated conversion option	11,525	—
Proceeds from revolver	12,500	15,000
Repayment of revolver	(2,500)	—
Repayment of prior term loan, net	—	(25,550)
Repayment of 3.75% senior notes	(13,022)	—
Debt issuance costs	(3,107)	(6,239)
Repurchase of 3.75% senior notes	(2,686)	(53,123)
Proceeds from exercise of common stock options and warrants	—	251
Principal payments on capital lease obligations	(11)	(6)
Net cash provided by financing activities	30,449	25,333
Effect of exchange rate on cash, cash equivalents and restricted cash	(714)	(860)
Net increase (decrease) in cash, cash equivalents and restricted cash	3,827	(13,236)
Cash, cash equivalents and restricted cash at beginning of year	13,069	27,165
Cash, cash equivalents and restricted cash at end of year	$ 16,182	$ 13,069
Supplemental Cash flow information:		
Cash payments for interest	$ 5,633	$ 7,340
Cash payments for income taxes	150	89
Non cash investing and financing transactions:		
Acquisition of capital expenditures in accounts payable and accrued expenses	46	568
Capitalized stock compensation in capital expenditures	28	96
Issuance of stock to consultant	—	102

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

TELIGENT, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the years ended December 31, 2019 and 2018
(in thousands, except share information)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance, January 1, 2018	53,400,281	$ 554	$ 106,312	$ (60,094)	$ (2,019)	$ 44,753
Issuance of stock to consultant	25,000	—	102	—	—	102
Stock based compensation expense			2,066	—	—	2,066
Stock options exercised	239,000	2	249	—	—	251
Issuance of stock for vested restricted stock units	109,940	1	(1)	—	—	—
Fair value of conversion feature on Convertible 4.75% Senior Notes			18,658			18,658
Partial extinguishment of equity component of Convertible 3.75% Senior Notes			(10,522)			(10,522)
Cumulative translation adjustment	—	—	—	—	(631)	(631)
Net loss	—	—	—	(36,256)	—	(36,256)
Balance, December 31, 2018	53,774,221	$ 557	$ 116,864	$ (96,350)	$ (2,650)	$ 18,421
Stock based compensation expense	—	—	1,104	—	—	1,104
Issuance of stock for vested restricted stock units	76,206	1	(1)	—	—	—
Cumulative translation adjustment	—	—	—	—	292	292
Net loss	—	—	—	(25,124)	—	(25,124)
Balance, December 31, 2019	53,850,427	558	$ 117,967	$ (121,474)	$ (2,358)	$ (5,307)

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

1. Nature of the Business and Going Concern

Nature of the Business

Teligent, Inc. is a Delaware corporation incorporated in 1977 and is a specialty generic pharmaceutical company. Under its own label, the Company markets and sells generic topical and branded generic and generic injectable pharmaceutical products in the United States and Canada. In the United States, the Company currently markets 38 generic topical pharmaceutical products and four branded generic pharmaceutical products. In Canada, the Company sells over 32 generic and branded generic injectable products and medical devices. Generic pharmaceutical products are bioequivalent to their brand name counterparts. The Company also provides contract manufacturing services to the pharmaceutical, over-the-counter, ("OTC"), and cosmetic markets. The Company operates its business under one segment. Our common stock has traded on the Nasdaq Global Select Market, under the trading symbol “TLGT” since October 26, 2015.

Teligent also develops, manufactures, fills, and packages topical semi-solid and liquid products for branded and generic pharmaceutical customers, as well as the OTC and cosmetic markets. These products are used in a wide range of applications from cosmetics and cosmeceuticals to the prescription treatment of conditions like dermatitis, psoriasis, and eczema. Teligent received its certification of expanded facility in the fourth quarter of 2018 and continued to develop and file ANDAs with the FDA in 2019. As the Company continues to execute the expansion of its development and commercial base beyond topical generics to include injectable generics, complex generics and ophthalmic generics (what we call our “TICO strategy”), it will compete in other markets, including the ophthalmic generic pharmaceutical market, and expects to face other competitors.

Going Concern

ASU 205-40 – Presentation of Financial Statements – Going Concern requires management to evaluate an entity’s ability to continue as a going concern within one year after the date the financial statements are available for issuance. Specifically, management is required to evaluate whether the presence of negative conditions or events, when considered individually and in the aggregate, raise substantial doubt about an entity’s ability to continue as a going concern. Substantial doubt exists when it is probable that the entity will be unable to meet its obligations as they become due within one year after the date the financial statements are available for issuance. Management has identified the following negative conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern as of December 31, 2019:

- The Company has incurred significant losses and generated negative cash flows from operations in recent years and expects to continue to incur losses and generate negative cash flow for the foreseeable future. As a result, the Company had an accumulated deficit of $121.5 million, total principal amount of outstanding borrowings of $214.0 million, and limited capital resources to fund ongoing operations at December 31, 2019. These capital resources were comprised of cash and equivalents of $15.5 million at December 31, 2019 and the generation of cash inflows from working capital. The Company’s available capital resources may not be sufficient for it to continue to meet its obligations as they become due over the next twelve months if the Company cannot improve its operating results or increase its operating cash inflows. In the event these capital resources are not sufficient, the Company may need to raise additional capital through the sale of equity or debt securities, enter into strategic business collaboration agreements with other companies, seek other funding facilities, or sell assets. However, the Company cannot provide assurances that additional capital will be available on acceptable terms or at all. Moreover, if the Company is unable to meet its obligations when they become due over the next twelve months through its available capital resources, or obtain new sources of capital when needed, the Company may have to delay expenditures, reduce the scope of its manufacturing operations, reduce or eliminate one or more of its development programs, make significant changes to its operating plan or cease its operations. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

- As disclosed in Note 17-Subsequent Events, the Company is subject to certain financial covenants as set forth in the April 6, 2020 amendments to the Senior Credit Facilities. These financial covenants include a trailing twelve months (“TTM”) Minimum Revenue covenant that is required to be met each quarterly period from March 31, 2020 through December 31, 2020, a TTM Minimum Adjusted EBITDA that is required to be met each quarterly period from March 31, 2021 through maturity, and a minimum liquidity covenant tested at all times through the term of the agreement. These amendments supersede the financial covenants included in the original and amended agreements disclosed in Note 6-Debt. In the event the Company is unable to comply with these covenants, or obtain a waiver from its lenders, the lender shall have the right, but not the obligation, to permanently reduce the commitment in whole or in part or to declare all or any portion of the outstanding balance due and payable. Furthermore, in the event that outstanding

balances under the Ares Credit agreements are declared due and payable by the lender, the lenders of the 2023 Series A and Series B Unsecured Convertible Notes shall have the right, but not the obligation, to declare all of the outstanding balance due and payable as well. If the Company is unable to raise additional capital to meet these obligations, the Company may have to seek other strategic alternatives, including ceasing its operations. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

- In June 2019, the Company received a de-listing notice from the NASDAQ due to its share price being below $1.00 for 30 consecutive trading days. The notice specified that the Company's share price must trade above $1.00 per share for ten consecutive trading days prior to December 2, 2019 in order to prevent its common stock from being de-listed. For the 180 days preceding December 2, 2019 the Company's share price remained below $1.00. The Company requested a second 180-day extension. NASDAQ denied its request and the Company chose to file for an appeal. The Company was granted a hearing date for the end of January 2020. Subsequent to the appeal hearing, NASDAQ set a deadline of April 17, 2020 for the Company to regain compliance with NASDAQ's continuing listing requirements. In early March 2020 the COVID-19 global pandemic triggered a significant decline in global capital markets, including NASDAQ. In light of this significant decline, the Company requested NASDAQ to reconsider the April 17, 2020 deadline. NASDAQ agreed to the Company's request and set a new deadline to regain compliance by June 1, 2020. In January 2020, the Company's Board of Directors and shareholders approved a reverse stock split in the range of any whole number between five (5) and ten (10) to one (1). While the Company believes that the reverse stock split will ultimately increase its share price above $1.00 for the required ten consecutive trading days, it can provide no assurances that its shares will trade above $1.00 per share for the required time period. A de-listing from the NASDAQ would be a "Fundamental Change" under the Company's 2023 Series A and Series B Unsecured Convertible Notes which triggers a right by the holders to require the Company repurchase the Convertible Notes. In such an event, the Company would need to seek financing to repurchase the Convertible Notes and there is no guarantee that such financing would be available or on terms acceptable to the Company. If noteholders demanded a repurchase of the notes and the Company could not finance the repurchase, it would be in default under the Indentures governing the Convertible Notes, and in that event the lenders of the Ares Credit agreements would have the right, but not the obligation, to declare all of the outstanding balance under those agreements due and payable as well. Therefore, in the event of the Company's shares are de-listed from the NASDAQ, the Company would likely have to seek some combination of waivers from its lenders and noteholders and seek new capital through the sale of equity or debt securities. If the Company is unable to obtain such waivers or raise new capital to meet these obligations if they become due, it may have to seek other strategic alternatives, including ceasing operations. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying audited financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The Company consolidates the following entities: Igen, Inc., Teligent Pharma. Inc., Teligent Luxembourg S.à.r.l., Teligent OÜ and Teligent Canada Inc, in addition to the following inactive entities: Microburst Energy, Inc., Blood Cells, Inc. and Flavorsome, Ltd. All inter-company accounts and transactions have been eliminated. Certain amounts in the prior periods presented have been reclassified to conform to the current period financial statement presentation. These reclassifications have no effect on previously reported net income.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include the valuation of the derivative liability associated with certain Notes, sales returns and allowances, allowances for excess and obsolete inventories, allowances for doubtful accounts, provisions for income taxes and related valuation allowances, stock based compensation, the assessment for the impairment of long-lived assets (including intangibles, goodwill and property, plant and equipment), property, plant and equipment and legal accruals. The Company bases its estimates and assumptions on historical experience, known or expected trends and various other assumptions that it believes to be reasonable. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates.

Cash Equivalents

The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents to the extent the funds are not being held for investment purposes. Cash and cash equivalents include cash on hand and bank demand deposits used in the Company's cash management program.

The Company has restricted cash, consisting of escrow accounts and letter of credits, which are included within other long-term assets on the Consolidated Balance Sheet. In addition, pursuant to the New Credit Facilities agreement, proceeds from the 2023 Term Loan were deposited in a blocked bank account and restricted for use for the sole purpose of repurchasing the outstanding 2019 Notes. During the first quarter of 2019, the Company used a total of $2.7 million of restricted cash to repurchase a portion of the remaining 2019 Notes. The remaining 2019 Notes were settled on their maturity (Note 6).

The Company presents restricted cash with cash and cash equivalents in the Consolidated Statement of Cash Flows. The following table provides a reconciliation of cash and cash equivalents and restricted cash reported in the Consolidated Balance Sheet to the total amounts in the Consolidated Statement of Cash Flows as follows (in thousands):

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 15,508	$ 9,705
Restricted cash	206	2,892
Restricted cash in other assets	468	472
Cash, cash equivalents and restricted cash in the statement of cash flows	$ 16,182	$ 13,069

Inventories

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

Property, Plant and Equipment

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

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

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

Intangible Assets

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

such assets exceeds its respective fair value and would be recorded in selling, general and administrative expense on the Consolidated Statements of Operations.

In-Process Research and Development

Amounts allocated to in-process research and development ("IPR&D") in connection with a business combination are recorded at fair value and are considered indefinite-lived intangible assets subject to annual impairment testing. As products in development are approved for sale, the associate balance will be allocated to product rights and amortized over their estimated useful lives. These valuations reflect, among other things, the impact of changes to the development programs, the projected development and regulatory time frames and the current competitive environment. The IPR&D are solely those assets acquired in the 2015 business combination of Alveda. The Company performed its annual impairment test and does not believe an impairment existed as of December 31, 2019.

Long-Lived Assets

In accordance with the provisions of ASC 360-10-55, the Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. In performing such review for recoverability, the Company compares expected future cash flows of assets to the carrying value of the long-lived assets and related identifiable intangibles. If the expected future cash flows (undiscounted) are less than the carrying amount of such assets, the Company recognizes an impairment loss for the difference between the carrying value of the assets and their estimated fair value, with fair values being determined using projected discounted cash flows at the lowest level of cash flows identifiable in relation to the assets being reviewed.

Product Acquisition Costs

Product acquisition costs represent ANDAs and NDAs acquired in asset acquisitions, which are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. The Company expects to amortize these costs over a 10-year useful life commencing when the product is sold. At December 31, 2019, product acquisition costs included assets acquired from AstraZeneca, Valeant and Sebela. The Company performed its annual impairment test and does not believe an impairment existed as of December 31, 2019.

Goodwill

Goodwill, which represents the excess of purchase price over the fair value of the net assets acquired, is carried at cost. Goodwill is tested for impairment on an annual basis on October 1 of each fiscal year or more frequently if events or changes in circumstances indicate that the asset might be impaired. The Company early adopted ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): "Simplifying the Test for Goodwill Impairment" in the fourth quarter of 2019. This amendment eliminates Step Two of the goodwill impairment test. Under the amendments in this update, an entity has the option to perform a qualitative assessment to determine if the quantitative impairment test is required. If the quantitative impairment test is required, the Company would perform the annual goodwill impairment test by comparing the carrying value of its reporting unit to its fair value. An impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value would be recorded. In accordance with the amendment, the Company performed the qualitative impairment test on October 1, 2019 and concluded its Goodwill was not impaired.

The carrying value of goodwill at December 31, 2019 was $0.5 million. We believe it is unlikely that there will be a material change in the future estimates or assumptions used to test for impairment losses on goodwill. However, if actual results were not consistent with our estimates or assumptions, we could be exposed to an impairment charge.

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, 2019 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.

As of December 31, 2019, based on level 2 inputs, the fair value of our 2023 Notes was approximately$23.0 million compared to their carrying value of $53.1 million and the fair value of our 2023 Series B Notes was approximately $28.9 million including the derivative liability of $6.8 million as mentioned below.

As of December 31, 2019, based on level 3 inputs, the fair value of the derivative liability associated with our 2023 Series B Notes was $6.8 million. (Note 7).

Debt Issuance Costs

Expenses related to debt financing activities are capitalized and amortized on an effective interest method, over the term of the loan and are to be netted against the carrying value of the financial liability, as required by ASU 2015-3. This standard aligns the treatment of debt issuance costs and debt discounts in that both reduce the carrying value of the liability. Amortization of debt issuance costs are recorded as interest expense on the Consolidated Statement of Operations.

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 aforementioned 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.

Contract Manufacturing Sales:

The Company recognizes revenue for contract manufacturing sales over-time, as milestones are achieved. Shipments are made in accordance with sales commitments and related sales orders entered into with customers either verbally or in written form.

Contract manufacturing sales are recognized net of accruals for cash discounts and returns which are established at the time of sale, and are included in Revenue, net in the Company's Consolidated Statement of Operations.

Research and Development Income:

The Company establishes agreed upon product development agreements with its customers to perform product development services. Revenues are recognized in accordance with the agreement upon the completion of the phases of development and when the Company has no future performance obligations relating to that phase of development. Other types of revenue include royalty or licensing revenue, which would be recognized over time, or at a point in time, based upon the contractual term upon completion of the earnings process. Judgments are required to evaluate contingencies such as potential variances in schedule and the costs, the impact of change orders, liability claims, contract disputes and achievement of contractual performance standards.

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 estimates 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. The Company reviews the percentage of products sold through these programs utilizing chargeback data and applies the appropriate program percentages to calculate the rebate accrual. Rebate invoices and/or payments may be received monthly, quarterly or annually and reviewed against the accruals. Other items that could be included in accrued rebates represent 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.

Accounts receivable are presented net of SRA balances of $30.5 million and $18.1 million at December 31, 2019 and 2018, respectively. The allowance for doubtful accounts was $2.2 million and $2.6 million at December 31, 2019 and 2018, respectively. These balances are primarily related to one specific customer in the amount of $1.7 million.

Additionally, the Company markets and distributes four products under its own label in the U.S., where in accordance with an agreement entered into in December of 2011, the Company is required to pay a royalty calculated based on net sales to one of its pharmaceutical partners. The royalty is calculated based on contracted terms of 40% of net sales for the four products, which is to be paid quarterly to its partner. Accounts payable and accrued expenses include $0.4 million and $0.2 million at December 31, 2019 and 2018, respectively, related to these royalties. Royalty expense of $1.4 million and $2.2 million was included in cost of goods sold for the years ended December 31, 2019 and 2018 respectively. The Company includes significant estimates to arrive at the respective net product sales for wholesaler chargebacks, Medicaid and Medicare rebates, allowances and other pricing and promotional programs.

Concentration of Risk

Financial instruments, which subject the Company to concentration of credit risk, consist primarily of cash equivalents and trade receivables. The Company maintains its cash in accounts with quality financial institutions. Although the Company currently believes that the financial institutions with which the Company does business will be able to fulfill their commitments to us, there is no assurance that those institutions will be able to continue to do so.

Major customers of the Company are defined as those constituting greater than 10% of our total revenue. In 2019, we had sales to two customers which individually accounted for more than 10% of our total revenue. These customers had sales of $17.6 million and $9.6 million respectively, which represented 41% of total revenues in the aggregate. Accounts receivable related to these major customers comprised of 25% and 6% respectively, and represented 31% of all accounts receivable as of December 31, 2019. 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.

Diflorasone Diacetate Ointment USP 0.05% accounted for 15% of the Company's total revenues in 2019. There was no product which individually accounted for more than 10% of the total revenues in 2018.

For the year ended December 31, 2019, domestic net revenues were $48.4 million and foreign net revenues were $17.5 million. As of December 31, 2019, domestic assets were $154.3 million and foreign assets were $52.6 million. 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 assets were $132.7 million and foreign assets were $58.2 million.

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

Acquisitions

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

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

Accounts Receivable and Allowance for Doubtful Accounts

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.

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.

Foreign Currency Translation

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

Foreign exchange loss of $1.5 million was recorded for the year ended December 31, 2019, 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, the Company will continue to record a non-cash gain or loss on translation for the remainder of the term of these loans. Due to the nature of this transaction, there is no economic benefit to the Company to hedge these transactions.

Accounting for Environmental Costs

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

Income Taxes

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

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

Stock-Based Compensation

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

Product Development and Research

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

Shipping and Handling Costs

Costs related to shipping and handling are comprised of outbound freight and the associated labor. These costs are recorded in costs of sales. For the years ended December 31, 2019 and 2018, the costs relating to shipping and handling totaled $1.8 million and $2.1 million, respectively.

Loss per Common Share

Basic loss per share of common stock is computed based on the weighted average number of shares of common stock outstanding during the period. Diluted loss per share of common stock is computed using the weighted average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period. Potential dilutive common stock equivalents include shares issuable upon the conversion of the notes and the exercise of options and warrants. Due to the net loss for the years ended December 31, 2019 and 2018, the effect of the Company's potential dilutive common stock equivalents was anti-dilutive; as a result, the basic and diluted weighted average number of common shares outstanding and net loss per common share are the same. As of December 31, 2019 and 2018, the shares of common stock issuable in connection with stock options and warrants have been excluded from the diluted loss per share, as their effect would have been anti-dilutive.

For the years ended December 31, 2019 and 2018
(in thousands except shares and per share data)

	2019	2018
Basic loss per share computation:		
Net loss attributable to common stockholders —basic and diluted	$ (25,124)	$ (36,256)
Weighted average common shares —basic and diluted	53,839,139	53,592,930
Basic and diluted loss per share	$ (0.47)	$ (0.68)

Adoption of Other Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which supersedes the existing lease guidance under Topic 840. The new standard requires lessees to recognize Right-of-Use ("ROU") assets and lease liabilities for all leases with terms greater than 12 months, including those leases that were previously classified as operating leases. Topic 842 retains a distinction between finance leases and operating leases, with measurement and presentation of expenses and cash flows being dependent upon the classification. The Company adopted the new standard effective January 1, 2019 utilizing the optional transition method allowed under ASU 2018-11, Leases (Topic 842): Targeted Improvements. The Company elected to adopt the package of practical expedients allowed under the new accounting guidance, which allows the Company to not reassess previous conclusions regarding 1) whether existing or expired leases are or contain leases, 2) the lease classification of existing or expired leases and 3) initial direct costs for existing leases. In addition, the Company adopted the practical expedient to combine lease and non-lease components for all classes of underlying assets. Per the requirements of the standard, the Company recorded a ROU asset and a lease liability representing the present value of future lease payments to be paid in exchange of the use of an asset of $1.9 million and $2.0 million respectively as of January 1, 2019. However, there was no cumulative effect

adjustment to the opening balance of retained earnings as the assets and the liabilities recorded upon adoption off-set each other.

In February 2018, the FASB issued ASU 2018-02, “Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income,” which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. This guidance is effective for all entities for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. The amendments in ASU 2018-02 should be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act is recognized. The Company's adoption of this amendment, effective January 1, 2019, did not have a material impact on its consolidated financial statements and the related disclosures.

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808): “Clarifying the Interaction between Topic 808 and Topic 606”. The guidance clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer. For the Company, the amendment will be effective on January 1, 2020, with early adoption permitted. The Company early adopted this amendment in the last quarter of 2019. The adoption of this amendment did not have a material impact on the Company's consolidated financial statements and the related disclosures.

In January 2017, the FASB issued ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): “Simplifying the Test for Goodwill Impairment”. The update simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. In accordance with the amendment, entities should perform the annual goodwill impairment test by comparing the carrying value of their reporting units to their fair value. An entity should record an impairment charge for the amount by which its carrying amount exceeds its reporting unit’s fair value. The Company early adopted the amendment in the fourth quarter of 2019. The adoption of this amendment did not have a material impact on the Company's consolidated financial statements and the related disclosures.

Recently Issued and Not Yet Adopted Accounting Pronouncements

In December 2019, the FASB issued accounting standard update to simplify the accounting for income taxes. The standard’s amendments include changes in various subtopics of accounting for income taxes including, but not limited to, accounting for “hybrid” tax regimes, tax basis step-up in goodwill obtained in a transaction that is not a business combination, intraperiod tax allocation exception to incremental approach, ownership changes in investments, interim-period accounting for enacted changes in tax law, and year-to date loss limitation in interim-period tax accounting. The guidance is effective for fiscal years beginning after December 15, 2020 with early adoption permitted, including the interim periods within those years. The Company is evaluating the impact this guidance will have on the Company’s Consolidated Financial Statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (“ASU No. 2016-13”), which requires that a financial asset (or a group of financial assets) measured at an amortized cost basis be presented at the net amount expected to be collected. This approach to estimating credit losses applies to most financial assets measured at amortized cost and certain other instruments, including but not limited to, trade and other receivables. The amendments in this update are originally effective for public business entities for fiscal years beginning after December 15, 2019. The Financial Accounting Standards Board subsequently postponed the effective date for small reporting companies to January 2023, which for the Company means January 1, 2023. Based on the current status of the evaluation, the Company believes the adoption of the guidance will not have a material impact on its Consolidated Financial Statements and related disclosures. The Company expects to continue and finalize its evaluation and assessment as required by the guidance upon adoption.

3. Inventories

Inventories as of December 31, 2019 and 2018 consisted of (in thousands):

	2019	2018
Raw materials	$ 14,117	$ 10,456
Work in progress	133	116
Finished goods	10,989	8,391
Inventories reserve	(2,208)	(2,667)
Inventories, net	$ 23,031	$ 16,296

4. Property, Plant and Equipment

Property, plant and equipment, at cost, as of December 31, 2019 and 2018, consisted of (in thousands):

	2019	2018
Land	401	$ 401
Building and improvements	58,959	53,813
Machinery and equipment	14,897	12,229
Computer hardware and software	4,771	4,182
Furniture and fixtures	705	694
Construction in progress	30,759	30,949
	110,492	102,268
Less accumulated depreciation and amortization	(14,143)	(10,493)
Property, plant and equipment, net	$ 96,349	$ 91,775

The Company recorded depreciation expense of $3.7 million and $2.6 million in 2019 and 2018, respectively. The Company capitalized the interest expense of $4.4 million as construction in progress during the twelve months ended December 31, 2018 and received a certificate of completion of its building in the fourth quarter of 2018. There was no interest expense capitalized as construction in progress during the twelve months ended December 31, 2019. In addition, during the twelve months ended December 31, 2019 and 2018, there were $1.2 million and $1.8 million respectively, of payroll costs capitalized as construction in progress.

5. Leases

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which supersedes the existing lease guidance under Topic 840. The new standard requires lessees to recognize Right-of-Use ("ROU") assets and lease liabilities for all leases with terms greater than 12 months, including those leases that were previously classified as operating leases. Topic 842 retains a distinction between finance leases and operating leases, with measurement and presentation of expenses and cash flows being dependent upon the classification. The Company adopted the new standard on January 1, 2019 utilizing the optional transition method allowed under ASU 2018-11, Leases (Topic 842): Targeted Improvements.

The Company elected to adopt the package of practical expedients allowed under the new accounting guidance, which allows the Company to not reassess previous conclusions regarding (1) whether existing or expired leases are or contain leases, (2) the lease classification of existing or expired leases and (3) initial direct costs for existing leases. In addition, the Company adopted the practical expedient to combine lease and non-lease components for all classes of underlying assets.

The Company reviewed its portfolio of lease agreements, and other service contracts to identify embedded leases, and reached conclusions on key accounting assessments related to the standard and finalized the related accounting policies. As a result of the implementation of the new standard, all leases with a term greater than 12 months previously classified as operating leases and only expensed through the Consolidated Statements of Operations are now recorded on the Consolidated Balance Sheets. Per the requirements of the standard, the Company has recorded a ROU asset and a lease liability representing the present value of future lease payments to be paid in exchange of the use of an asset of $1.9 million and $2.0 million, respectively as of January 1, 2019. However, there was no cumulative effect adjustment to the opening balance of retained earnings as the assets and the liabilities recorded upon adoption off-set each other.

We have operating and finance leases for our corporate, manufacturing and international facilities as well as certain equipment. Our leases have remaining terms of less than 1 year to up to ten years, including available options to extend some of our lease terms for up to 5 years. One of our lease agreements has an early termination option within one year. As the interest rates implicit in our leases are typically not readily determinable, the Company has elected to utilize an incremental borrowing rate as the discount rate, determined based on the expected term of the lease, the Company's credit risk and existing borrowings. The discount rates utilized ranged from 4.86% to 8.60% and were utilized to determine the present value of the lease liabilities.

The components of lease expense were as follows:

	Year ended December 31, 2019
Operating lease cost	$ 635
Finance lease cost:	
Amortization of right-of-use assets	$ 14
Interest on lease liabilities	$ 6
Total finance lease cost	$ 20

Right-of-use assets obtained in exchange for new operating lease liabilities were $1.0 million during the year ended December 31, 2019. Cash paid for amounts included in the measurement of operating lease liabilities during the year ended December 31, 2019 was $0.6 million. Cash paid for amounts included in the measurement of finance lease liabilities during the three months and year ended December 31, 2019 was not material.

Supplemental balance sheet information related to leases were as follows:

	December 31, 2019
Operating Leases	
Other assets	$ 2,453
Other current liabilities	434
Other long-term liabilities	2,199
Total operating lease liabilities	2,633
Finance Leases	
Property, plant, and equipment	81
Accumulated depreciation	(12)
Property, plant, and equipment, net	69
Other current liabilities	12
Other long-term liabilities	57
Total finance lease liabilities	$ 69

The weighted average remaining lease terms for operating and financing leases are 6.3 years and 4.7 years, respectively. The weighted average discount rates for operating and finance leases are 8.2% and 8.0%, respectively.

As of December 31, 2019 maturities of lease liabilities were as follows:

Year Ending December 31,	Operating Leases	Financing Leases
2020	$ 635	$ 18
2021	610	18
2022	550	18
2023	549	18
2024	236	12
Thereafter	843	—
Total lease payments	3,423	84
Less imputed interest	790	15
Total	$ 2,633	$ 69

As previously disclosed in our 2018 Annual Report on Form 10-K and under the previous lease accounting standard, future minimum lease payments for operating leases having initial or remaining non-cancelable lease terms in excess of one year would have been as follows:

	Commitments
2019	$ 573
2020	611
2021	633
2022	610
2023	607
2024	200
	$ 3,234

6. Debt

Convertible Notes

2019 Notes, 2023 Notes and 2023 Series B Notes

On December 16, 2014, the Company issued $125.0 million aggregate principal amount of the 2019 Notes. On December 22, 2014, the Company announced the closing of the initial purchasers' exercise in full of their option to purchase an additional $18.75 million aggregate principal amount of the 2019 Notes. The 2019 Notes bore 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 matured on December 15, 2019, unless earlier repurchased, redeemed or converted. The 2019 Notes were convertible into shares of the Company's common stock, cash or a combination thereof. On May 20, 2015, the Company received shareholder approval for the increase in the number of shares of common stock authorized and available for issuance upon possible conversion of the 2019 Notes.

On April 27, 2018, the Company 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 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 the Company's common stock, cash or a combination thereof. The initial conversion rate is $4.45 per share, subject to certain adjustments, related to either the Company's 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. The Company incurred debt issuance 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, the Company 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. The Company allocated the total amount of debt issuance costs incurred to the liability and equity components using the same proportions as the proceeds from the 2023 Notes. The debt issuance 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 11.9%.

The exchange of $75.1 million of the 2019 Notes for the 2023 Notes is considered a debt extinguishment under ASC 470-50. The 2019 Notes are accounted for under cash conversion guidance ASC 470-20, which requires the Company 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. In accordance with the aforementioned guidance, the Company allocated a portion of the $75.1 million to the extinguishment of the liability component equal to the fair value of that component immediately before extinguishment and recognized a $2.5 million extinguishment loss in the Consolidated Statement of Operations to measure the difference between (i) the fair value of the liability component and (ii) the net carrying amount of the liability component (which is already net of any unamortized debt issuance costs). In addition, the Company recorded a $7.6 million reduction of Additional Paid in Capital in connection with the extinguishment of $75.1 million of the 2019 Notes.
In December 2018 the Company used $52.8 million of proceeds from the Senior Credit Facilities (see below) to repurchase a portion of the 2019 Notes as well as $0.3 million of proceeds to pay for transaction costs. The repurchase of the 2019 Notes is considered a debt extinguishment under ASC 470-50. The 2019 Notes are accounted for under cash conversion guidance ASC 470-20, which requires the Company 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. In accordance with the guidance above, the Company allocated a portion of the $52.8 million to the extinguishment of the liability component equal to the fair value of that component immediately before extinguishment and recognized a $1.7 million extinguishment loss in the Consolidated Statement of Operations to measure the difference between (i) the fair value of the liability component and (ii) the net carrying value amount of the liability component (which is already net of any unamortized debt issuance costs). In

addition, the Company recorded a $2.9 million reduction of Additional Paid in Capital in connection with the extinguishment of the 2019 Notes.

In the beginning of 2019, the Company used a total of $2.7 million of proceeds from the Senior Credit Facilities to repurchase a portion of the remaining 2019 Notes. The repurchase of the 2019 Notes is considered a debt extinguishment under ASC 470-50. The 2019 Notes are accounted for under cash conversion guidance ASC 470-20, which requires the Company 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. In accordance with the guidance above, the Company allocated a portion of the $2.7 million to the extinguishment of the liability component equal to the fair value of that component immediately before extinguishment and recognized a $0.2 million extinguishment loss in the Consolidated Statement of Operations to measure the difference between (i) the fair value of the liability component and (ii) the net carrying value amount of the liability component (which is already net of any unamortized debt issuance costs). The reduction of Additional Paid in Capital in connection with this extinguishment was immaterial. The Company settled the remaining 2019 Notes of $13.0 million in principal upon its maturity in December 2019.

2023 Series B Notes

On October 31, 2019, the Company closed its offering of the 2023 Series B Notes in the aggregate principal amount of $34.4 million. The 2023 Series B Notes will mature in May 2023 and are convertible at the option of the holder at any time prior to maturity at an initial conversion price of $0.72 per share, subject to adjustment under certain circumstances. The 2023 Series B Notes and any shares of common stock issuable upon conversion of the 2023 Series B Notes (the “Conversion Shares”) have not been registered under the Securities Act of 1933, as amended (the “Securities Act”), or any state or other jurisdiction’s securities laws, and the 2023 Notes and the Conversion Shares may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Securities Act and applicable state or other jurisdictions’ securities laws. The Company does not intend to file a registration statement for the resale of the 2023 Series B Notes or any Conversion Shares.

As part of the offering, the Company entered into agreements with certain holders of its existing 2023 Notes to exchange $9.0 million of the 2023 Notes for $5.1 million of the 2023 Series B Notes. The gross cash proceeds of approximately $29.3 million from the financing were used to extinguish the Company’s existing 2019 Notes in December 2019 and intended to pay amounts owing with respect to other indebtedness and to fund general corporate and working capital requirements. The 2023 Series B Notes bear interest at a rate of 7.00% per annum if paid in cash, semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2020. The Company also has an option, and has agreed with its senior lender, to PIK the interest at 8.00% per annum, to defer cash payments. The net proceeds from the financing were $26.9 million after deducting a total of $2.3 million of the initial purchasers’ discounts and professional fees associated with the transaction.

Under ASC 470-60, Troubled Debt Restructurings by Debtors, the exchange of the $9.0 million of the 2023 Notes for the $5.1 million of the 2023 Series B Notes represents a troubled debt restructuring ("TDR"). The TDR did not result in a gain recognition. As a result, a new effective interest rate was established based on the $7.2 million carrying value of the original debt, net of the $2.0 million fair value of the embedded derivative liability related to the new debt issued in the TDR and $0.2 million issuance costs, getting accreted to $6.8 million representing the total amount of the future undiscounted cash flows related to the $5.1 million of the 2023 Series B Notes.

In accordance with ASC 815-15, Derivatives and hedging, Embedded Derivatives, the embedded conversion option should be bifurcated and separately accounted for as a derivative instrument, because the Company did not have enough authorized shares available to share-settle the conversion option. Such derivative instruments should be initially and subsequently measured at fair value, with changes in fair value recognized in earnings (see Note 7). The derivative liability recorded at the issuance date was $13.5 million, including the $2.0 million above accounted for in the TDR, which was subsequently remeasured to $6.8 million as of December 31, 2019, with $6.8 million recognized as a gain on change in fair value of derivative in the Company's statement of operations. Further, the $0.9 million of allocated issuance costs associated with the bifurcated conversion features embedded in the notes was recognized as a loss on debt restructuring in the Company’s statement of operations for the year ended December 31, 2019. In accordance with ASC 470-20, the initial carrying amount of the liability component of the 2023 Series B Notes, excluding the $5.1 million portion above is accounted for as a TDR, upon issuance is the residual amount between total proceeds from the transaction and the derivative liability net of allocated issuance costs. The $1.4 million debt issuance costs attributable to the liability component were recorded as a direct deduction from the liability component of the 2023 Series B Notes and are being amortized to interest expense using the effective interest method through the maturity date. The discount from the par amount of the 2023 Series B Notes will be accreted to par utilizing the effective-interest rate method over the term of the Notes from the issuance date through May 2023. The effective interest rate of the 2023 Notes, inclusive of the debt discount and issuance costs is 27.4%.

Prior Term Loan

On June 1, 2018, the Company entered into a credit agreement for $25.0 million in original principal amount of term loans secured by all Company assets (the "Prior Term Loan"). The Prior Term Loan incurred debt issuance costs of $0.5 million and a debt discount of $0.4 million. The debt discount is due to lender fees paid on the initial drawdown of $15.0 million. The debt issuance costs and debt discount were amortized to interest expense using the effective interest method through the maturity date. In December 2018, the Company used $25.6 million of proceeds from the Senior Credit Facilities (see below) to repay the Prior 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 Prior Term Loan is considered a debt extinguishment under ASC 470-50. In 2018, the Company recorded $1.3 million of extinguishment loss related to the repayment of the Prior Term Loan in the Consolidated Statement of Operations.

Senior Credit Facilities

On December 13, 2018 we entered into the Senior Credit Facilities, consisting of the Revolver and Term Loans. The Senior Credit Facilities also included a $15.0 million delayed draw term loan b commitment, which remained undrawn and expired on October 31, 2019. As of December 31, 2019, $25.0 million was drawn under the Revolver and $88.5 million of Term Loans were outstanding. As of December 31, 2019, the Revolver was fully drawn. The Company extended commitments related to undrawn amounts of the Delayed Draw Term Loan A from June 30, 2019 to December 13, 2019, pursuant to an amendment the Company entered with the Second Lien Agent on July 18, 2019. The extended Delayed Draw Term Loan A was subsequently drawn down by the Company in December 2019. Drawn amounts under the Delayed Draw Term Loans mature at the same time as the Initial Term Loan. The Term Loans mature on the earliest to occur of the June 23, 2024 and the date of that is 181 days prior to the maturity date of each of (x) the 2023 Notes and (y) the 2023 Series B Notes. The Revolver matures on the earliest to occur of the June 23, 2024 and the date of that is 91 days prior to the maturity date of each of (x) the 2023 Notes and (y) the 2023 Series B Notes. The Company's 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 the Company's assets. All of the Company's debt is subordinated to the Senior Credit Facilities. The liens securing the Term Loans are subordinate to the liens securing the Revolver. The Senior Credit Facilities had 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 which were superseded by the amendments noted below. The financial covenants consisted of a minimum revenue test, a minimum adjusted EBITDA test and a maximum total net leverage ratio.

The Revolver bears interest at a fluctuating rate of interest equal to one, two, three or six-month LIBOR plus a margin of 3.75% or a rate based on the prime rate plus a margin of 2.75%. The Term Loans bear interest at a fluctuating rate of interest equal to one, two, three or six-month LIBOR plus a margin of 8.75% or a rate based on the prime rate plus a margin of 7.75%. Interest on the Senior Credit Facilities is payable in cash quarterly in arrears (or more frequently in connection with customary LIBOR interest provisions), provided, that the Company may elect (and has covenanted to the lenders under its First Lien Credit Agreement to) pay interest on the Term Loans in kind until the earlier to occur of the date upon which Company has provided financial statements demonstrating twelve-months of revenue of at least $125.0 million and (ii) December 28, 2020.

Amounts drawn under the Revolver may be prepaid at the option of the Company without premium or penalty, subject, in the case of acceleration of the Revolver or termination or reduction 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 Revolver are subject to mandatory prepayment to the extent that aggregate extensions under the 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 Term Loans may be prepaid at the option of the Company 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 Revolver as a result of any corresponding mandatory prepayment requirements thereunder, amounts outstanding under the 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.

In connection with the Revolver the Company incurred a debt discount of $0.5 million and debt issuance issue costs of $0.3 million. The debt discount is due to annual fees and lender fees paid on the initial drawdown of $15.0 million. The debt issuance costs and debt discount are recorded as an asset on the Consolidated Balance Sheet and are amortized to interest expense using the straight-line method through the estimated Revolver maturity date. The annual fees related to the Revolver

and the Initial Term Loan are amortized to interest expense using the straight-line method over the annual period they relate to. In connection with the Initial Term Loan and Delayed Draw Term Loan A, the Company incurred a debt discount of $1.8 million and debt issuance issue costs of $0.8 million. The debt discount is due to lender fees paid on the Initial Term Loan of $50.0 million and drawdown of Delayed Draw Term Loan A of $20.0 million. The debt issuance costs and debt discount costs are amortized to interest expense using the effective interest rate method through the estimated maturity date. In addition, the Company incurred $0.5 million of debt issuance costs related to the commitment fees paid to the lenders for the undrawn amounts of the Delayed Draw Term Loans. These debt issuance costs are recorded as an asset on the balance sheet and amortized on a straight-line basis over the access period of the Delayed Draw Term Loans through June 30, 2019. The effective interest rates, inclusive of the debt discounts and issuance costs, for the various borrowing tranches of the Revolver were between 6.2% and 9.1%. The effective interest rates, inclusive of the debt discounts and issuance costs for the Initial Term Loan and Delayed Draw Term Loan A were between 9.1% and 12.2%.

The Initial Term Loan of $50.0 million and $15.0 million of the Revolver were drawn by the Company on December 13, 2018. On December 21, 2018, the Company drew $20.0 million of the Delayed Draw Term Loan A. In January 2019, the Company drew $5.0 million and subsequently the remaining $5.0 million under the Revolver were drawn down by the Company in April 2019. On September 18, 2019, pursuant to terms of the First Lien Credit Agreement, the Company borrowed an advance in the aggregate principal amount of $2.5 million (the “Protective Advance”). The Protective Advance is a secured Obligations under the First Lien Credit Agreement, and bears interest at the rate applicable to the Revolver. The Protective Advance was subsequently repaid in November 2019 along with a repayment fee of $0.1 million. The Company drew down the remaining $10.0 million under its borrowing capacity of Delayed Draw Term Loan A before its expiry in December of 2019. The $15.0 million Delayed Draw Term Loan B expired upon the issuance of the 2023 Series B Notes, prior to the Company drawing down any monies.

The Term Loans are governed by the Second Lien Credit Agreement. The Term Loans include a 24-month paid-in-kind interest option available to the Company should it choose to defer cash payments in order to maintain the liquidity needed to continue launching new products, and preparing for an FDA prior approval inspection of its new injectable manufacturing facility. The Company has elected the paid-in-kind interest option and increased the principal balance of Term Loans by $8.5 million for the twelve month periods ended December 31, 2019 respectively.

On April 6, 2020, the Company entered into amendments pertaining to the Senior Credit Facilities. The amendments collectively among other things, (i) increase the interest rates on April 6, 2020, (ii) reset certain prepayment premiums and modify the terms of certain mandatory prepayments and (iii) modify certain financial covenant levels inclusive of the disposition of prior covenants as of and for the period ended December 31, 2019. Additional information pertaining to the Senior Credit Facilities amendments is included in the Subsequent Event footnote.

At December 31, 2019 and December 31, 2018, the net carrying amount of the debt and the remaining unamortized debt discounts and debt issuance costs were as follows (in thousands):

	December 31, 2019	December 31, 2018
	(Current)	(Current)
Face amount of the 2019 Notes (due December 2019)	$ —	$ 15,702
Less unamortized discounts and debt issuance costs	—	1,291
Total net carrying value	$ —	$ 14,411

	December 31, 2019	December 31, 2018
Face amount of the 2023 Notes (due May 2023)	$ 66,090	$ 75,090
Face amount of the Revolver Credit Facility (due December 2022)	25,000	15,000
Face amount of the 2023 Series B Notes (due May 2023)	34,405	—
Face amount of the 2023 Loan (due February 2023)	88,464	70,000
Total carrying value, non-current	$ 213,959	$ 160,090
Less unamortized discounts and debt issuance costs	27,589	20,519
Total net carrying value, non-current	$ 186,370	$ 139,571

Debt Maturities Schedule

Aggregate maturities of the Company’s debt are presented below (in thousands):

Year Ending December 31,	
2022	25,000
2023	188,959
Total	$ 213,959

7. Derivatives

The Company accounts for its derivative instruments in accordance with ASC 815-10, “Derivatives and Hedging”. ASC 815-10 establishes accounting and reporting standards requiring that derivative instruments, including derivative instruments embedded in other contracts, be recorded on the balance sheet as either an asset or liability measured at its fair value. ASC 815-10 also requires that changes in the fair value of derivative instruments be recognized currently in results of operations unless specific hedge accounting criteria are met.

The Company has not entered into hedging activities to date. The Company's derivative liability at December 31, 2019 was the embedded convertible option of its 2023 Series B Notes issued on October 31, 2019, which has been recorded as a liability at fair value and was revalued at each reporting date, with changes in the fair value of the instruments included in the consolidated statements of operations as non-operating income (expense). The Company does not have a derivative liability at December 31, 2018.

The terms and assumptions used in connection with the valuation of the convertible option of the 2023 Series B Notes are as follows:

		Initial Measurement		Measurement
Measurement date		10/31/2019		12/31/2019
Issuance date		10/31/2019		10/31/2019
Maturity date		5/1/2023		5/1/2023
Term (years)		3.5		3.33
Principal	$	34,405	$	34,405
Coupon		7.00% cash/ 8.0% PIK		7.00% cash/ 8.0% PIK
Seniority		Senior unsecured		Senior unsecured
Conversion price	$	0.72	$	0.72
Stock price	$	0.63	$	0.43
Risk free rate		1.5 %		1.6 %
Volatility		47.3 %		47.3 %

The following table presents the Company’s liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2019.

	Quoted Prices in Active markets for Identical Assets and Liabilities	Significant Other Observable Inputs	Significant Unobservable Inputs	Balance as of December 31, 2019
Descriptions	(Level 1)	(Level 2)	(Level 3)	
Derivative liability related to Series B Convertible Notes	—	— $	6,776 $	6,776

The following table sets forth a summary of changes in the fair value of the Company’s Level 3 liabilities for the year ended December 31, 2019. Any unrealized gains or losses on the derivative liabilities are recorded as non-operating income or expense in the Company’s statement of operations.

	Initial Measurement	Subsequent Measurement	Balance as of
Descriptions	10/31/2019	(Gain) or loss recognized in earnings from Change in Fair Value	12/31/2019
Fair value of convertible feature of Series B Convertible Notes	$ 13,545	$ (6,769)	$ 6,776

8. Revenues, Recognition and Allowances

Revenue Recognition

As of January 1, 2018, the Company adopted the ASC 606 guidance for revenue recognition for contracts, using the modified retrospective method. The implementation of this guidance had no material impact on the measurement or recognition of revenue from customer contracts of prior periods.

Upon adoption of this new guidance, the Company recognizes revenue using the following five steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price, including the identification and estimation of variable consideration;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when we satisfy a performance obligation.

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.

Revenue is recognized 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. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price using the expected value method based on historical experience as well as applicable information currently available.

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.

Contract Manufacturing Sales

The Company recognizes revenue for contract manufacturing sales over-time, as milestones are achieved. Shipments are made in accordance with sales commitments and related sales orders entered into with customers either verbally or in written form.

Contract manufacturing sales are recognized net of accruals for cash discounts and returns which are established at the time of sale, and are included in Revenue, net in the Company's Consolidated Statement of Operations.

Research and Development Services and Other Income

The Company establishes agreed upon product development agreements with its customers to perform product development services. Revenues are recognized in accordance with the agreement upon the completion of the phases of development and when the Company has no future performance obligations relating to that phase of development. Other types of revenue include royalty or licensing revenue, which would be recognized over time, or at a point in time, based upon the contractual term upon completion of the earnings process. Judgments are required to evaluate contingencies such as potential variances in the schedule or the costs, the impact of change orders, liability claims, contract disputes and achievement of contractual performance standards.

Revenues by Transaction Type

The Company operates in one reportable segment and, therefore, the results of the Company's operations are reported on a consolidated basis, consistent with internal management reporting for the chief decision maker. Net Sales (in thousands) for the three years ended December 31, 2019 and 2018 were as follows (prior-period amounts are not adjusted under the modified-retrospective method of adoption):

	Years ended December 31,	
	2019	2018
Company product sales	$ 64,291	$ 59,591
Contract manufacturing sales	1,362	6,047
Research and development services and other income	243	227
Revenue, net	$ 65,896	$ 65,865

Disaggregated information for the Company product sales revenue has been recognized in the accompanying audited Consolidated Statements of Operations, and is presented below according to contract type (in thousands):

	Years ended December 31,	
Company Product Sales	**2019**	**2018**
Topical	$ 46,150	$ 35,118
Injectables	18,141	24,473
Total	$ 64,291	$ 59,591

For the twelve months ended December 31, 2019, Company did not incur, and therefore did not defer, any material incremental costs to obtain contracts.

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, 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.

Accounts receivable are presented net of returns and allowances of $30.5 million and $18.1 million at December 31, 2019 and 2018, respectively. The allowance for doubtful accounts was $2.2 million and $2.6 million at December 31, 2019 and 2018, respectively. These allowances are primarily related to one specific customer in the amount of $1.7 million.

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 estimate 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 the 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 or quarterly

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 revenue and accounts receivable balances in the Company's consolidated financial statements are presented net of sales and returns and allowances (SRA) estimates. Certain SRA balances are included in accounts payable and accrued expenses.

The Company's adjustments for the deductions to gross product sales for the two years ended December 31, 2019 and 2018 are as follows (in thousands):

	Years ended December 31,	
	2019	2018
Gross product sales	$ 156,301	$ 158,278
Reduction to gross product sales:		
Chargebacks and billbacks	60,008	60,770
Wholesaler fees for service	9,000	5,503
Sales discounts and other allowances	23,002	32,414
Total reduction to gross product sales	$ 92,010	$ 98,687
Total product sales, net	$ 64,291	$ 59,591

9. Goodwill and Intangible Assets

Goodwill

The Company acquired the assets of Canadian pharmaceutical company Alveda Pharmaceuticals, Inc., in November 2015. As a result of the acquisition, goodwill of $0.4 million was recorded. Our annual impairment test is conducted annually on October 1. Goodwill is also tested for impairment whenever an event occurs or circumstances change that would more likely than not reduce the fair value of its reporting unit below its carrying amount. There have been no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value and therefore no impairment losses have been recognized pertaining to goodwill.

Changes in goodwill during the two years ended December 31, 2019 and December 31, 2018 were as follows (in thousands):

	Goodwill
January 1, 2018	$ 471
Foreign currency translation	(1)
December 31, 2018	470
Foreign currency translation	21
December 31, 2019	$ 491

Intangible Assets

The following sets forth the major categories of the Company's intangible assets and the weighted-average remaining amortization period as of December 31, 2019 and December 31, 2018 for those assets that are not already fully amortized (in thousands):

	December 31, 2019			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted Average Remaining Amortization Period
Trademarks and Technology	$ 39,943	$ (10,885)	$ 29,058	10.8
Product acquisition costs	13,103	—	13,103	N/A - See description below
In-process research and development ("IPR&D")	327	—	327	N/A - See description below
Customer relationships	3,658	(1,501)	2,157	5.9
Total	$ 57,031	$ (12,386)	$ 44,645	

	December 31, 2018			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted Average Remaining Amortization Period
Trademarks and Technology	$ 40,169	$ (8,239)	$ 31,930	11.8
Product acquisition costs	13,308	—	13,308	N/A - See description below
In-process research and development ("IPR&D")	719	—	719	N/A - See description below
Customer relationships	3,557	(1,139)	2,418	6.9
Total	$ 57,753	$ (9,378)	$ 48,375	

Changes in intangibles during the year ended December 31, 2019 were as follows (in thousands):

	Product Acquisition Costs	Trademarks and Technology	IPR&D	Customer Relationships
Balance at December 31, 2018	$ 13,308	$ 31,930	$ 719	$ 2,418
Amortization	—	(2,646)	—	(362)
Intangible assets placed in service	—	301	(301)	—
Foreign currency translation	(205)	(527)	(91)	101
Balance at December 31, 2019	$ 13,103	$ 29,058	$ 327	$ 2,157

The Company recorded amortization expense of $3.0 million and $3.1 million in 2019 and 2018, respectively. The Company recorded an impairment loss of $0.7 million and $1.2 million related with product acquisition costs and IPR&D, respectively, in 2018. There were no impairment losses pertaining to intangibles for the year ending December 31, 2019.

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

Year ending December 31,	Amortization Expense *
2020	$ 3,008
2021	3,008
2022	3,008
2023	3,008
2024	3,008
Thereafter	16,175
Total	$ 31,215

*IPR&D and Product Acquisition Costs are not included in the table.

The useful lives of the Company's intangible assets are as follows:

Intangibles Category	Amortizable Life
Product Acquisition Costs	10 years
Trademarks & Technology	15 years
Customer Relationships	10 years

10. Stock-Based Compensation

Stock Options

The 1999 Director Stock Option Plan, as amended (the "Director Plan"), provides for the grant of stock options to non-employee directors of the Company at an exercise price equal to the fair market value per share on the date of the grant. As of May 25, 2016, this plan is no longer active for grants. There were 485,000 and 500,000 stock options outstanding as of December 31, 2019 and 2018, respectively.

On June 26, 2009, the Board of Directors adopted, and the Company's stockholders subsequently approved by written consent, the IGI Laboratories, Inc. 2009 Equity Incentive Plan (the "2009 Plan"). The 2009 Plan became effective on July 29, 2009 and was no longer active for grants subsequent to May 25, 2016. The 2009 Plan allowed the Company to grant options and restricted stock, as well as the Board of Directors to authorize a broad range of other equity-based awards, including stock appreciation rights, restricted stock units ("RSUs") and performance awards to consultants, service providers, employees and board members. On April 12, 2010, the Board of Directors adopted, and the Company's stockholders subsequently approved, an amendment and restatement of the 2009 Plan to increase the number of shares of Common Stock available for grant under such plan by adding 2,000,000 shares of Common Stock. The 2009 Plan, as amended on May 29, 2010, authorizes up to 5,000,000 shares of the Company's common stock for issuance pursuant to the terms of the 2009 Plan. The maximum number of shares that may be subject to awards made to any individual in any single calendar year under the 2009 Plan is 1,000,000 shares. There were 1,847,608 stock options outstanding and 1,868,302 shares of stock outstanding as of December 31, 2019. There were no RSUs outstanding at December 31, 2019. There were 14,377 RSUs, 1,853,925 shares of stock outstanding and 2,458,106 stock options outstanding as of December 31, 2018. As of December 31, 2019, 1,369,038 options available were transferred to the superseded plan.

On May 25, 2016, the Board of Directors approved the Company's 2016 Equity Incentive Plan (the "2016 Plan"). On May 21, 2018, the Board of Directors adopted, and the Company's stockholders subsequently approved, an amendment and restatement of the 2016 Plan to increase the number of shares of Common Stock available for grant under such plan by adding 2,000,000 shares of Common Stock. The 2016 Plan, as amended, provides for the issuance of awards of up to 4,000,000 shares of the Company's common stock, plus any currently forfeited, expired or canceled grants without delivery of shares of common stock to the recipient which would be returned to the plan for reissuance up to 2,500,000 shares. Generally, shares of common stock reserved for awards under the 2016 Plan that lapse or are canceled, will be added back to the share reserve available for future awards. However, shares of common stock tendered in payment for an award or shares of common stock withheld for taxes will not be available again for grant. The 2016 Plan provides that no participant may receive awards for more than 1,000,000 shares of common stock in any fiscal year. As the 2016 Plan supersedes either the Director Plan or the 2009 Plan, any available shares from either are now incorporated into the 2016 Plan. As of December 31, 2019, there were 62,680 RSUs outstanding, 136,496 shares of common stock outstanding and 2,835,131 stock options under the 2016 Plan. As of December 31, 2018, there were 161,214 RSUs outstanding, 74,667 shares of common stock outstanding and 1,394,285 stock options outstanding under the 2016 Plan. As of December 31, 2019 and December 31, 2018, there were 5,167,739 and 4,352,391 stock options

outstanding respectively in the Director Plan, 2009 Plan, and the 2016 Plan. As of December 31, 2019, there were 2,334,731 options available to grant under the plan.

In the interest of maintaining consistency with the Company's 2016 Equity Incentive Plan, on March 13, 2017, the Company entered into (i) an amendment to the option agreements governing each option grant currently outstanding under the Company's 2009 Equity Incentive Plan, and (ii) an amendment to the RSU agreements governing each RSU grant then outstanding under the 2009 Plan. The amendments provide for the automatic vesting upon a change of control of the Company of each option grant and RSU grant, as applicable, outstanding under the 2009 Plan. The amendments had a de minimis value to the holders as of December 31, 2019, and therefore no additional stock compensation expense was recognized related to the amendments.

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

Assumptions	**2019**	**2018**
Expected dividends	0 %	0 %
Risk free rate	1.38 - 2.47%	2.44 %
Expected volatility	64.33 - 76.81%	52.7 - 72.5%
Expected term (in years)	3.2 – 3.3 years	3.2 – 3.3 years

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

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

	Shares	**Exercise Price Per Share**	**Weighted Average Exercise Price**
January 1, 2018 shares issuable under options	4,299,810	$0.79 - $10.67	$ 5.09
Granted	839,785	1.73-4.25	3.34
Exercised	(239,000)	1.02-1.83	1.05
Expired	—	—	—
Forfeited	(548,204)	2.02-10.67	8.04
December 31, 2018 shares issuable under options	4,352,391	$0.79-$10.67	$ 4.61
Granted	2,468,129	$0.55-$1.80	0.61
Exercised	—	—	—
Expired	(761,780)	$1.02-$10.67	2.42
Forfeited	(891,001)	$0.66-$8.67	1.04
December 31, 2019 shares issuable under options	5,167,739	$0.55-$10.67	$ 3.34

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2019:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number of Options	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
$0.00 - $0.78	195,155	9.58	$ 0.65	—	$ —
$0.79 - $1.50	1,781,369	4.52	1.02	1,265,000	1.03
$1.51 - $5.50	1,884,517	8.25	2.27	482,288	3.30
$5.51 - $10.67	1,306,698	5.97	8.44	1,250,518	7.73
Total	5,167,739	6.44	$ 3.34	2,997,806	$ 4.49

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2018:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number of Options	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
$0.79 - $1.50	1,510,000	3.12	$ 1.06	1,510,000	$ 1.06
$1.51 - $5.50	992,457	8.27	3.23	199,826	2.76
$5.51 - $10.67	1,849,934	6.99	8.24	1,528,686	8.45
Total	4,352,391	5.94	$ 4.61	3,238,512	$ 4.65

The Company has recorded $0.9 million, $1.5 million related to its stock option based compensation expenses in cost of sales, product development and research expenses, and selling, general and administrative expenses on the accompanying Consolidated Statements of Operations for the years ended December 31, 2019 and 2018, respectively.

The aggregate intrinsic value of options outstanding was $0.0 million at December 31, 2019 and $0.5 million at December 31, 2018. The aggregate intrinsic value of the options exercisable was $0 million at December 31, 2019 and $0.5 million at December 31, 2018. The total intrinsic value of the options exercised during 2019 and 2018 was $0 million, $0.1 million, respectively.

A summary of non-vested options at December 31, 2019 and changes during the year ended December 31, 2019 is presented below:

	Options	Weighted Average Grant Date Fair Value
Non-vested options at January 1, 2019	1,113,878	$ 2.00
Granted	2,468,129	0.61
Vested	(521,073)	2.20
Forfeited	(891,001)	1.04
Non-vested options at December 31, 2019	2,169,933	$ 0.77

As of December 31, 2019, there was $1.0 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements under the Plan. The costs will be recognized through November 2022.

Restricted Stock and RSUs

The Company periodically grants restricted stock and RSU awards to certain officers and other employees that typically vest one to three years from their grant date. The Company recognized $0.2 million and $0.5 million, respectively, of compensation expense during the years ended December 31, 2019 and 2018 related to restricted stock awards and RSUs. Stock compensation

expense is recognized over the vesting period of the restricted stock and RSUs. At December 31, 2019, the Company had approximately $0.1 million of total unrecognized compensation cost related to non-vested restricted stock and RSUs, all of which will be recognized through March 2021.

There have been no restricted stock issuances in the years ended 2019 and 2018.

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

	Number of RSUs	Weighted Average Issuance Price
Non-vested balance at January 1, 2018	188,629	$8.27
Changes during the period:		
Shares granted	122,949	3.36
Shares vested	(109,940)	8.95
Shares forfeited	(26,047)	5.76
Non-vested balance at December 31, 2018	175,591	$4.78
Changes during the period:		
Shares granted	—	—
Shares vested	(76,206)	5.39
Shares forfeited	(36,705)	4.74
Non-vested balance at December 31, 2019	62,680	$4.07

11. Accrued Expenses

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

For the fiscal years ended December 31, 2019, and 2018, the largest components of accrued expenses were (in thousands):

	2019	2018
Professional fees	$ 1,881	$ 2,153
Payroll	1,789	1,908
Interest expense	1,539	1,042
Medicaid and Medicare	987	383
Rebates	774	714
Wholesaler Fees	747	203
Royalties	377	222
Clinical Studies	334	334
Inventory and supplies	250	1,809
Income Tax	20	45
Capital expenditures	23	275
Other	564	754
	$ 9,285	$ 9,842

12. Income Taxes

The Company is subject to U.S. federal income tax and files a consolidated federal income tax return which includes all eligible U.S. subsidiary companies. The Company is also subject to tax in the states of Alabama, Illinois, Montana, New Jersey and

Tennessee. The Company conducts significant operations in certain foreign countries and is, accordingly, subject to tax in those foreign jurisdictions consisting of Canada (including the province of Ontario), Estonia, Luxembourg and Jersey.

Loss before income tax for the years ended December 31, 2019 and 2018 consisted of the following (in thousands):

	2019	2018
U.S. operations	$ (20,212)	$ (32,183)
Foreign operations	(4,821)	(4,135)
Global Total	$ (25,033)	$ (36,318)

The Company's current tax expense (benefit) was $0.1 million and $(0.1) million for the years ended December 31, 2019 and 2018, respectively. The provision (credit) for income taxes attributable to continuing operations before income taxes for the years ended December 31, 2019 and 2018 is as follows (in thousands):

	2019	2018
Current tax expense (benefit):		
Federal	$ —	$ —
State and local	23	30
Foreign	87	(157)
Total current tax expense (benefit)	110	(127)
Deferred tax expense:		
Federal	—	—
State and local	—	—
Foreign	(19)	65
Total deferred tax (benefit) expense	(19)	65
Total income tax expense (benefit)	$ 91	$ (62)

A comparison of income tax (benefit) expense at the U.S. statutory rate of 21% in 2019 and 2018 to the Company's effective rate is as follows (in thousands):

	2019	2018
Expected Statutory benefit	$ (5,257)	$ (7,627)
Other non-deductible expenses	133	256
Change in valuation allowance	4,674	6,572
Research credits	(504)	—
Tax rate differential - foreign vs. U.S.	1,073	791
State income taxes, net of federal benefit	18	23
Prior year true-up	(45)	(93)
Exchange gain	(1)	16
	$ 91	$ (62)

During the fourth quarter of 2018, the Company completed its full assessment and finalized the accounting for the impact of the United States Tax Cuts and Jobs Act (U.S. TCJA) and concluded that there was no additional impact.

Deferred tax balances included in the Consolidated Balance Sheets as of December 31, 2019 and 2018 consisted of the following (in thousands):

	2019	2018
Deferred Tax Assets:		
Sales allowances and doubtful accounts	$ 2,991	$ 1,964
Inventory reserve	652	962
Deferred revenue	—	590
Accrued expenses	206	23
Property, plant and equipment	272	258
Tax operating loss carryforwards	10,851	9,951
Tax credit and other carryforwards	5,996	1,299
Stock compensation	566	538
Total deferred tax assets	21,534	15,585
Less valuation allowance	(18,562)	(12,120)
Net deferred tax assets	2,972	3,465
Deferred Tax Liabilities:		
Convertible debt conversion features	(3,070)	(3,514)
Foreign exchange	(14)	(28)
Intangible assets	(93)	(138)
Total deferred tax liabilities	(3,177)	(3,680)
Net deferred tax liability	$ (205)	$ (215)

The Company evaluates the recoverability of its deferred tax assets based on its history of operating results, its expectations for the future, and the expiration dates of the net operating loss carry forwards. Based on the preponderance of the evidence, the Company has concluded that it is more likely than not that it will be unable to realize the net deferred tax assets in the immediate future and has established a full valuation allowance for substantially all deferred tax assets. Accordingly, the Company has provided a valuation allowance of $18.6 million and $12.1 million for the years ended December 31, 2019 and 2018, respectively, on its deferred tax assets. The valuation allowance increased $6.5 million during 2019. This increase was due to $5.6 million related to changes in deferred taxes and $0.9 million related to the 2019 net operating loss.

Operating loss, tax credit and other carry forwards as of December 31, 2019 and 2018 were as follows (in thousands):

	2019	2018
Federal:		
Net operating losses (see below)	$ 48,531	$ 45,081
Disallowed interest expense (no expiration)	17,783	5,018
Contributions (expiring through 2024)	658	524
Research tax credits (expiring through 2026)	1342	135
State:		
New Jersey (expiring in 2039)	4,942	2,976
Other states (expiring through 2039)	3,266	2,307
New Jersey research credits (expiring in 2026)	764	—
Foreign		
Net operating losses (no expiration)	$ —	$ 257

At December 31, 2019, the Company’s U.S. federal net operating loss carryforwards will expire as follows (in thousands):

Year	Net Operating Loss
2020 - 2023	$ 8,227
2024 - 2029	9,063
2030 - 2032	9,926
2033 - 2036	6,296
2037	8,116
No expiration but subject to limitation	6,903
Total	$ 48,531

Federal net 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.

The Company's ability to use net operating loss carry forwards is subject to substantial limitation in future periods under certain provisions of Section 382 of the Internal Revenue Code of 1986, as amended, which limit the utilization of net operating losses upon a more than 50% change in ownership of the Company's stock that is held by 5% or greater stockholders. The Company examined the application of Section 382 with respect to an ownership change that took place during 2010, as well as the limitation on the application of net operating loss carry forwards. The Company believes that operating losses subsequent to the change date in 2010 (aggregating $26.5 million) are not subject to Section 382 limitations. The Company has estimated that the annual limitation starting in 2010 aggregates from $1.0 million to $2.3 million per year including the effect of amortization of built in gains. The Company's loss carryforwards may be further limited in the future if additional ownership changes occur.

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

Federal income tax returns for the years 2014 and 2015 have been examined by the U.S. Internal Revenue Service without any income tax expense consequences. For federal purposes (except for the years 2014 and 2015), post 1998 tax years remain open to examination as a result of net operating loss carryforwards. The Company is currently open to audit by the appropriate state income taxing authorities for tax years 2014 through 2018. The Company has not recorded any liability for uncertain tax positions at December 31, 2019 or December 31, 2018.

13. Commitments

The Company's commitments and contingencies consisted of leases for warehouse, office space and equipment. See Note 6 Leases for future lease payments under non-cancellable leases.

The Company has certain licensing and development agreement in place under which the Company will pay certain licensing fees and milestones over the lives of certain projects. These commitments totaled approximately $2.4 million as of December 31, 2019, and will be paid over the next several years in accordance with agreed upon milestones.

14. Legal and U.S. Regulatory Proceedings

To date, thirteen 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 pharmaceuticals, including econazole nitrate. 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 pharmaceuticals from as early as July 1, 2009 until the time the defendants' allegedly unlawful conduct ceased or will cease. The class plaintiffs seek treble damages for alleged overcharges during the alleged period of conspiracy, and certain of the class plaintiffs also seek injunctive relief against the defendants. The 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. On December 19, 2019 certain class plaintiffs filed a further complaint that included additional claims against the Company based on the Company's sales of fluocinolone acetonide. A motion to dismiss this complaint has not yet been filed.

“Opt-out” antitrust lawsuits have additionally been filed against the Company by various plaintiffs, including Humana Inc.; The Kroger Co. et al.; United HealthCare Services, Inc.; Molina Healthcare, Inc.; MSP Recovery Claims, Series LLC; Health Care Service Corp.; and Harris County, Texas. All but one of these complaints have been 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 up to forty-seven defendants (including the Company) and involves allegations regarding the pricing of econazole along with up to 180 other drug products, most of which 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 some 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 remaining opt-out complaints has not yet been filed.

Due to the early stage of these cases, 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 these cases are without merit and it intends 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. The arbitrator has issued an interim award finding that the Company is not liable to Stayma on two of Stayma’s three claims against the Company. The third claim will proceed to a damages phase. The Company has argued that Stayma did not suffer any damages related to this claim and will vigorously pursue complete dismissal of the third claim. In addition, the arbitrator will determine money damages owed by Stayma to the Company relating to Stayma’s failure to pay several past due invoices of approximately $1.7 million.

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 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 the claims against Teligent are without merit, and it intends to vigorously defend against them.

On April 15, 2019 a federal class action was filed the Oklahoma Police Pension Fund and Retirement System against the Company and certain individual defendants in the U.S. District Court, Southern District of New York. The lawsuit was brought on behalf of persons or entities who purchased or otherwise acquired publicly-traded Teligent, Inc. securities from March 7, 2017 through November 6, 2017. The complaint alleges that defendants made false or misleading statements regarding the Company’s business, operational, and compliance policies in violation of U.S. securities laws. The plaintiff seeks to recover compensable damages. Due to the early stage of these cases, 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 these cases are without merit and it intends to vigorously defend against these claims.

15. Employee Benefits

The Company has a 401(k) contribution plan, pursuant to which employees may elect to contribute to the plan, in whole percentages, up to 100% of compensation. Employees’ contributions are subject to a maximum contribution of $19.0 thousand for 2019 and $18.5 thousand for 2018, plus a catch-up contribution of up to for $6.0 thousand for 2019 and 2018, if a participant qualifies. The Company matches 100% of the first 3% of compensation contributed by participants and 50% of the next 2% of compensation contributed by participants. The Company contribution is in the form of cash, which is vested immediately. The Company has recorded charges to expense related to this plan of $368.7 thousand and $358.2 thousand in 2019 and 2018, respectively.

16. Quarterly Results (Unaudited)

The following is a summary of certain quarterly financial information for the fiscal years 2019 and 2018:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
	(in thousands, except per share data)				
Year Ended December 31, 2019					
Total revenues, net	$ 13,122	$ 18,341	$ 18,466	$ 15,967	$ 65,896
Gross profit	5,762	8,541	7,280	1,940	23,523
Operating loss	(2,740)	686	209	(6,175)	(8,020)
Net loss	(8,724)	(3,989)	(7,113)	(5,298)	(25,124)
Net loss attributable to common stockholders	(8,724)	(3,989)	(7,113)	(5,298)	(25,124)
Basic loss per share	$ (0.16)	$ (0.08)	$ (0.13)	$ (0.10)	$ (0.47)
Diluted loss per share	$ (0.16)	$ (0.08)	$ (0.13)	$ (0.10)	$ (0.47)
Year Ended December 31, 2018					
Total revenues, net	$ 14,545	$ 16,249	$ 18,294	$ 16,777	$ 65,865
Gross profit	5,220	4,784	6,719	5,662	22,385
Operating loss	(3,531)	(4,910)	(1,213)	(5,445)	(15,099)
Net loss	(4,802)	(13,119)	(3,945)	(14,390)	(36,256)
Net loss attributable to common stockholders	(4,802)	(13,119)	(3,945)	(14,390)	(36,256)
Basic loss per share	$ (0.09)	$ (0.25)	$ (0.07)	$ (0.27)	$ (0.68)
Diluted loss per share	$ (0.09)	$ (0.25)	$ (0.07)	$ (0.27)	$ (0.68)

17. Subsequent Events

COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of novel coronavirus disease ("COVID-19") as a pandemic, and we expect our operations in all locations to be affected as the virus continues to proliferate. We have adjusted certain aspects of our operations to protect our employees while avoiding business interruption. Only employees essential to the production and quality control aspects of our products remain on-site at our manufacturing and production facility in Buena, New Jersey. The outbreak and any preventative or protective actions that we, our customers, suppliers or other third parties with which we have business relationships, or governments may take in respect of the COVID-19 outbreak could disrupt our business and the business of our customers. Global health concerns, such as COVID-19, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. In addition, the COVID-19 outbreak could result in a severe economic downturn and has already significantly affected the financial markets of many countries. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including our ability to raise capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our suppliers or third party CMOs, possibly resulting in supply disruption, or cause our customers to delay purchases or payments for our products. The COVID-19 pandemic may also create delays in the review and approval of our regulatory submissions as well as our pending reinspection related to our warning letter and pre-approval inspection for commercial production on the newly installed injectable line at the Company's New Jersey facility by the FDA.

We have initiated more frequent and detailed communications with our suppliers and the tracking of customer orders and wholesaler sell through data to help identify breaks in trends which may either facilitate the better servicing of our customers or negatively impact the achievement of our targets at risk. We will continue to monitor the situation closely and react accordingly to any future restrictions or limitations, while keeping the health of our employees and the interest of our customers and business in mind. Due to the uncertainty in the severity and duration of the pandemic, the impact on our revenues, profitability and statement of financial position is uncertain at this time.

Senior Credit Facilities Amendment

On April 6, 2020 (the "Amendment Closing Date"), the Company entered (i) Amendment No. 2 of the Revolver and Amendment No. 4 of the Term Loans, effective as of December 31, 2019. The amendments collectively among other things, (i) increase the interest rates, (ii) reset certain prepayment premiums and modify the terms of certain mandatory prepayments and (iii) modify certain financial covenant levels inclusive of the disposition of prior covenants as of and for the period ended December 31, 2019.

The associated increase in interest rates are effective as of the Amendment Closing Date. The Revolver bears interest at a fluctuating rate of interest equal to the one, two, three or six-month LIBOR plus a margin of 5.5% or a rate based on the prime rate plus a margin of 4.5%, with a LIBOR floor of 1.5%. The Term Loans bear interest at a fluctuating rate of interest equal to the one, two, three or six-month LIBOR plus a margin of 13.0% or a rate based on the prime rate plus a margin of 12.0%, with a LIBOR floor of 1.5%. Interest on the Senior Credit Facilities is payable in cash quarterly in arrears (or more frequently in connection with customary LIBOR interest provisions), provided, that the Company may elect (and has covenanted to the lenders under its Senior Credit Facilities and subsequent amendments thereto) to pay interest on the Term Loans in kind through December 13, 2021 but only if the following occurs: (1) the Company receives a "warning letter close-out letter" from the Federal Drug Administration in response to corrective actions taken by the Company since receipt of the warning letter in November 2019 and (2) the Company receives a written recommendation from the Federal Drug Administration setting forth its approval decision in respect of the pre-approval inspection for commercial production on the newly installed injectable line at the Company's New Jersey facility. If only one of those items occurs by December 13, 2020, then the Company may still elect to pay interest in kind during 2021, but only from the time the second condition has been satisfied until December 13, 2021. Thereafter, a portion of interest on the loans accruing at a rate of 4.25% per annum may continue to be paid in kind.

Both amendments provide that in the event of receipt of net proceeds from a disposition triggering a mandatory prepayment, net proceeds of such disposition will be applied as follows: (i) first, to be retained by the Company or applied

to amounts outstanding under the First Lien Credit Agreement until such time as liquidity of the Company and its subsidiaries equals $10.0 million, (ii) next to amounts outstanding under the Revolver (without a permanent reduction in the revolving loan commitments of the lenders) until such amounts are paid in full (with the first lien administrative agent having the right to waive such prepayment, in which event, such net proceeds are applied to amounts outstanding under the Second Lien Credit Agreement), and (iii) finally, to amounts outstanding under the Term Loans. In addition, pursuant to the Revolver, the Company has agreed at all times to maintain book cash of the Company and its subsidiaries not in excess of $10.0 million with any excess being required to prepay the outstanding obligations under the Revolver.

The following additions and changes to financial covenants set forth in both Amendments are: (i) a new minimum net revenue covenant is added that is tested on the last day of each fiscal quarter from March 31, 2020 until the quarter ending December 31, 2020, (ii) resets a minimum consolidated adjusted EBITDA covenant that is tested on the last day of each fiscal quarter ending during the period from March 31, 2021 to maturity, (iii) eliminates a total net leverage covenant and (iv) adds a minimum liquidity covenant tested at all times during the term of the Senior Credit Facilities.

In connection with the transactions contemplated by the Term Loan Amendment, on April 6, 2020, the Company issued to the Term Loan lenders certain warrants to purchase shares of the Company's common stock (collectively, the "Warrants"). The Warrants are exercisable for up to, in the aggregate, 5,389,949 of pre-reverse stock split shares of the Company's common stock at an exercise price of $0.01 per share of common stock. The Warrants will become exercisable at any time after the Company implements the reverse stock split previously approved by its stockholders and will remain exercisable, in whole or in part, for a period of five years.

The number of shares issuable upon the exercise of the Warrants is subject to customary adjustments upon the occurrence of certain events, including (i) payment of a dividend or distribution to holders of shares of the Company's common stock payable in shares of the Company's common stock, (ii) a subdivision, capital reorganization or reclassification of the Company's common stock or (iii) a merger, sale or other change of control transaction.

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

	Balance at Beginning of Year	Additions		Deductions	Balance at End of Year
		Charged to Costs and Expenses	Charged other Accounts		
Year Ended December 31, 2018					
Change in Tax Valuation Allowance	$ 13,309	67	(1,256)	—	$ 12,120
Allowance for Doubtful Accounts	$ 2,185	451	—	—	$ 2,636
Reserve for Inventory Obsolescence	$ 1,304	3,343	—	1,980	$ 2,667
Year Ended December 31, 2019					
Change in Tax Valuation Allowance	$ 12,120	(19)	6,461	—	$ 18,562
Allowance for Doubtful Accounts	$ 2,636	208	—	636	$ 2,208
Reserve for Inventory Obsolescence	$ 2,667	2,297	—	2,754	$ 2,210

DESCRIPTION OF CAPITAL STOCK OF TELIGENT, INC.

The following is a summary of all material characteristics of our capital stock as set forth in our amended and restated certificate of incorporation and amended and restated bylaws. The summary does not purport to be complete and is qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, which are incorporated by reference as exhibits to the Annual Report on Form 10-K to which this description is an exhibit.

Authorized Capital Stock

Our authorized capital stock consists of 100,000,000 shares of our common stock, $0.01 par value per share, and 1,000,000 shares of our preferred stock, $0.01 par value per share, of which 100 shares are designated as Series A Convertible Preferred Stock, 1,030 shares are designated as Series B-1 Convertible Preferred Stock, 798 shares are designated as Series B-2 Preferred Stock and 1,550 shares are designated Series C Convertible Preferred Stock.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Each election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any of our outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our amended and restated certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. There are no shares of preferred stock currently outstanding, and we have no present plans to issue any shares of preferred stock.

Options

As of March 23, 2020, we had outstanding options to purchase 8,133,582 shares of our common stock, at a weighted average exercise price of $2.25 per share.

Delaware Anti-Takeover Law and Certain Charter and Bylaw Provisions

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless either the interested stockholder attained such status with the approval of our board of directors, the business combination is approved by our board of directors and stockholders in a prescribed manner or the interested stockholder acquired at least 85% of our outstanding voting stock in the transaction in which it became an interested stockholder. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. The restrictions contained in Section 203 are not applicable to any of our existing stockholders that owned 15% or more of our outstanding voting stock upon the closing of our IPO.

Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that, except as otherwise required by law, special meetings of the stockholders can only be called by the chairman of our board of directors, our chief executive officer or our board of directors. In addition, our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock, because even if it acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholder meeting and not by written consent.

AMENDMENT NO. 1 TO SECOND LIEN CREDIT AGREEMENT

This AMENDMENT NO. 1 TO SECOND LIEN CREDIT AGREEMENT, dated as of February 8, 2019 (this "Amendment"), is by and among TELIGENT, INC., a Delaware corporation (the "Borrower"), its Subsidiaries signatory hereto as guarantors or hereafter designated as Guarantors pursuant to Section 8.11 of the Credit Agreement (as defined below), the lenders from time to time party hereto (each a "Lender" and, collectively, the "Lenders"), ARES CAPITAL CORPORATION, a Maryland corporation ("ARCC"), as administrative agent and collateral agent for the Lenders (in such capacity, together with its successors and assigns in such capacity, the "Administrative Agent"). For purposes of this Amendment, all terms used herein which are not otherwise defined herein, including but not limited to those terms used in the recitals hereto, shall have the respective meanings assigned thereto in the Amended Credit Agreement (as defined below).

WHEREAS, the Administrative Agent, Lenders, Borrower and other Credit Parties have entered into financing arrangements pursuant to which the Lenders (or Administrative Agent on behalf of the Lenders) have made and may make Loans and provide other financial accommodations to Borrower as set forth in (i) the Second Lien Credit Agreement, dated as of December 13, 2018 (as in effect prior to the effectiveness of this Amendment, the "Credit Agreement", and as the same is amended by this Amendment and as may be further amended, restated, supplemented or otherwise modified from time to time, the "Amended Credit Agreement"), by and among the Administrative Agent, Lenders, Borrower and other Credit Parties and (ii) the other Credit Documents, including, without limitation, this Amendment; and

WHEREAS, the Borrower, the Administrative Agent, and the Lenders desire to amend certain provisions of the Credit Agreement, as provided more fully herein.

NOW THEREFORE, in consideration of the foregoing premises and the mutual agreements and covenants contained in the Credit Agreement and herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

Section 1. Amendments to the Credit Agreement. Subject to the conditions to effectiveness set forth in Section 3 hereof, and in reliance upon the representations and warranties made by the Credit Parties in Section 2 hereof, pursuant to Section 12.01 of the Credit Agreement and subject to the terms and conditions herein, the Credit Agreement is hereby amended as set forth below in this Section 1.

1.01. Section 1.01 of the Credit Agreement is hereby amended:

(a) by inserting the following new definitions in their proper alphabetical order:

"'Consolidated Excess Cash Flow' shall mean, for a specified period, the excess (if any), of: (a) Consolidated Adjusted EBITDA for such period, less (b) the sum for such period (without duplication and to the extent that the following amounts have not already been deducted in determining Consolidated Adjusted EBITDA for such period) of (i) Consolidated Interest Expense paid in cash, (ii) scheduled principal payments of the Term Loans or other Indebtedness of the Borrower and its Subsidiaries (in respect of Indebtedness permitted under Section 9.01 hereof) made during such period to the extent paid in cash (and not financed, other than with the proceeds of loans funded under the First Lien Credit Agreement), (iii)

Taxes based on income paid in cash by the Borrower and its Subsidiaries, (iv) Consolidated Capital Expenditures made in cash during such period (and not financed, other than with the proceeds of loans funded under the First Lien Credit Agreement), (v) any costs, expenses and/or charges described in clause (b)(vii) or clause (b)(viii) of the definition of "Consolidated Adjusted EBITDA" to the extent paid in the cash during such period, (vi) the purchase price paid in cash for all Permitted Acquisitions to the extent paid in cash (and not financed, other than with the proceeds of loans funded under the First Lien Credit Agreement) and (vii) increases (or minus decreases) in Consolidated Working Capital for such period."

"'Consolidated Working Capital" shall mean, as of any date of determination, the excess of (a) the sum of all amounts (other than Cash and Cash Equivalents) that would, in conformity with GAAP, be set forth opposite the caption "total current assets" (or any like caption) on a consolidated balance sheet of Borrower and its Subsidiaries at such date over (b) the sum of all amounts that would, in conformity with GAAP, be set forth opposite the caption "total current liabilities" (or any like caption) on a consolidated balance sheet of Borrower and its Subsidiaries on such date, including deferred revenue but excluding, without duplication, (i) the current portion of any Funded Debt, (ii) all Indebtedness consisting of the Loans and loans under the First Lien Credit Agreement to the extent otherwise included therein, (iii) the current portion of interest and (iv) the current portion of current and deferred income Taxes.

1.02. Section 5.02(f) of the Credit Agreement is hereby amended and restated in its entirety as follows:

"(f) Subject to Section 5.02(i), amounts to be applied in connection with prepayments and Commitment reductions made pursuant to this Section 5.02, other than under subsection (l) of this Section, shall be applied, first, to the prepayment of the Term Loans, together with any accrued and unpaid interest thereon, until such Term Loans are repaid in full and, second, to the prepayment of any other outstanding Obligations. Each prepayment of the Loans under this Section 5.02, other than under subsection (l) of this Section, shall be accompanied by accrued interest to the date of such prepayment on the principal amount prepaid and the Prepayment Premium or Make-Whole Premium, as applicable.

1.03. Section 5.02(j) of the Credit Agreement is hereby amended and restated in its entirety as follows:

"(j) Notwithstanding the foregoing, each Lender may reject all or a portion of its Pro Rata Share of any mandatory prepayment (such declined amounts, the "Declined Proceeds") of any class of Term Loans required to be made pursuant to clauses (a), (b), (c), or (l) of this Section 5.02 by providing written notice (each, a "Rejection Notice") to the Administrative Agent and the Borrower no later than 1:00 p.m. one (1) Business Day after the date of such Lender's receipt of notice from the Administrative Agent regarding such prepayment (subject to extension by Administrative Agent in its sole discretion). Each Rejection Notice from a Lender shall specify the principal amount of the mandatory

prepayment of Term Loans to be rejected by such Lender. If a Lender fails to deliver a Rejection Notice to Administrative Agent within the time frame specified above or such Rejection Notice fails to specify the principal amount of the Term Loans to be rejected, any such failure will be deemed an acceptance of the total amount of such mandatory prepayment of such Term Loans. Any Declined Proceeds may be retained by the Borrower.

1.04. Section 5.02 of the Credit Agreement is hereby amended by adding thereto the following new Section:

"(l) On or prior to the earlier of (A) the fifth (5th) day after the delivery of annual financial statements for a fiscal year in accordance with Section 8.01(c) or (B) the ninety-fifth (95th) day of each year, in each case commencing with the fiscal year ending December 31, 2020, the Borrowers shall prepay the Loans in an amount equal to (x) fifty percent (50%) of Consolidated Excess Cash Flow (if any) for such fiscal year, to be applied as set forth in Section 5.02(f) less (y) all voluntary prepayments of Term Loans made during such fiscal year pursuant to Section 5.01, to be applied as set forth in Section 5.02(f)."

Section 2. Representations and Warranties. Each Credit Party, jointly and severally, hereby represents and warrants to the Lenders and the Administrative Agent as follows, which representations and warranties are continuing and shall survive the execution and delivery hereof:

2.01. No Default. At and as of the date of this Amendment and both prior to and after giving effect to this Amendment, no Default or Event of Default is continuing.

2.02. Representations and Warranties True and Correct. At and as of the date of this Amendment and both prior to and after giving effect to this Amendment, each of the representations and warranties contained in the Credit Agreement and other Credit Documents is true and correct in all material respects (except where such representations and warranties expressly relate to an earlier date, in which case such representations and warranties are true and correct in all material respects as of such earlier date).

2.03. Corporate Power and Authority. Each Credit Party has the corporate or other organizational power and authority to execute and deliver this Amendment and carry out the terms and provisions of this Amendment and the Amended Credit Agreement and has taken all necessary corporate or other organizational action to authorize the execution, delivery and performance of this Amendment and the performance of the Amended Credit Agreement. Each Credit Party has duly executed and delivered this Amendment, and this Amendment and the Amended Credit Agreement constitute the valid and binding agreements of such Credit Party enforceable in accordance with their respective terms, subject to applicable bankruptcy, insolvency, fraudulent conveyance, moratorium, reorganization and other similar laws relating to or affecting creditors' rights generally and general principles of equity (whether considered in a proceeding in equity or law).

2.04. No Violation. The execution, delivery and performance by any Credit Party of this Amendment and the performance of the Amended Credit Agreement, and compliance with the terms and provisions thereof, will not (i) contravene any applicable provision of any material Applicable Law of any Governmental Authority, (ii) result in any breach of any of the terms, covenants, conditions or

provisions of, or constitute a default under, or result in the creation or imposition of (or the obligation to create or impose) any Lien upon any of the property or assets of any Credit Party (other than Permitted Liens and Liens created under the Credit Documents) pursuant to (A) the terms of any material indenture, loan agreement, lease agreement, mortgage or deed of trust, or (B) any other Material Contracts Obligation, in the case of either clause (ii)(A) or (ii)(B), to which any Credit Party is a party or by which it or any of its property or assets is bound, or (iii) violate any provision of the Organization Documents of any Credit Party, except with respect to any conflict, breach or contravention or default (but not creation of Liens) referred to in clause (ii), to the extent that such conflict, breach, contravention or default could not reasonably be expected to have a Material Adverse Effect.

Section 3. Conditions. This Amendment shall become effective on the date upon which the Administrative Agent shall have received counterparts of this Amendment duly executed by each Credit Party and each other relevant party to this Amendment.

Section 4. Miscellaneous.

4.01. Fees and Expenses. The Borrower agrees and acknowledges that all reasonable and documented out-of-pocket costs and expenses incurred by the Administrative Agent in connection with this Amendment, including the reasonable fees, disbursements and other charges of one counsel), shall be paid by the Credit Parties to the Administrative Agent.

4.02. No Waiver or Modification. Nothing contained herein shall be deemed to constitute a waiver of compliance with any term or condition contained in the Credit Agreement or any other Credit Document or constitute a course of conduct or dealing among the parties. The Administrative Agent and Lenders reserve all rights, privileges and remedies under the Credit Documents. Except as expressly amended hereby, the Credit Agreement and other Credit Documents remain unmodified and in full force and effect in accordance with their respective terms and are hereby ratified and confirmed in all respects.

4.03. Credit Document. This Amendment shall constitute a Credit Document under and as defined in the Amended Credit Agreement. All references in the Credit Documents to the Credit Agreement shall be deemed to be references to the Credit Agreement as amended hereby.

4.04. Governing Law. THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND ANY CLAIM, CONTROVERSY OR DISPUTE UNDER, ARISING OUT OF OR RELATING TO THIS AMENDMENT, WHETHER BASED IN CONTRACT (AT LAW OR IN EQUITY), TORT OR ANY OTHER THEORY, SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

4.05. Counterparts. This Amendment may be executed by one or more of the parties hereto in any number of separate counterparts, each of which when so executed and delivered shall be deemed an original, but all such counterparts together shall constitute but one and the same instrument. Delivery of an executed counterpart of a signature page of this Amendment by facsimile or in electronic format (i.e., "pdf" or "tif") by electronic transmission shall be effective as delivery of a manually executed counterpart of this Amendment.

4.06. Headings. Section headings in this Amendment are included herein for convenience of reference only and shall not affect the interpretation of this Amendment.

4.07. Binding Effect; Assignment. This Amendment shall be binding upon and inure to the benefit of the Borrower, the other Credit Parties, the Administrative Agent and the Lenders and their respective successors and assigns in accordance with the terms of the Credit Agreement.

4.08. Integration. This Amendment, the Amended Credit Agreement, and the other Credit Documents incorporate all negotiations of the parties hereto with respect to the subject matter hereof and thereof and are the final expression and agreement of the parties hereto and thereto with respect to the subject matter hereof and thereof. This Amendment, the Amended Credit Agreement, and the other Credit Documents represent the agreement of the parties hereto with respect to the subject matter hereof and thereof, and there are no promises, undertakings, representations or warranties by any party hereto or thereto relative to the subject matter hereof or thereof not expressly set forth or referred to herein or therein.

4.09. Reaffirmation. Each Credit Party as debtor, grantor, pledgor, guarantor, assignor, or in any other similar capacity in which such Credit Party grants liens or security interests in its property or otherwise acts as accommodation party or guarantor, as the case may be, hereby (i) ratifies and reaffirms all of its payment and performance obligations, contingent or otherwise, under each Credit Document to which it is a party (after giving effect hereto) and (ii) to the extent such Credit Party granted liens on or security interests in any of its property pursuant to any such Credit Document as security for or otherwise guaranteed the Borrowers' Obligations under or with respect to the Credit Documents, ratifies and reaffirms such guarantee and grant of security interests and liens and confirms and agrees that such security interests and liens hereafter secure all of the Obligations as amended hereby.

[Remainder of the page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their respective officers thereunto duly authorized, as of the date first above written.

BORROWER:

TELIGENT, INC.

By:_____
Name: Jason Grenfell-Gardner
Title: Chief Executive Officer

GUARANTORS

IGEN, INC.

By:_____
Name: Jason Grenfell-Gardner
Title: Chief Executive Officer

TELIGENT PHARMA, INC.

By:_____
Name: Jason Grenfell-Gardner
Title: Chief Executive Officer

ADMINISTRATIVE AGENT AND A LENDER:

ARES CAPITAL CORPORATION,
a Maryland corporation

By: _____
Name: Scott Lem
Title: Authorized Signatory

LENDERS:

ACF FINCO I LP,
a Delaware limited partnership

By: _____
Name: Olek Szczupak
Title: Authorized Signer

CION ARES DIVERSIFIED CREDIT FUND

By: _____
Name:
Title:

ARES CENTRE STREET PARTNERSHIP, L.P.,

By: Ares Centre Street GP, Inc., as general partner

By: _____
Name:
Title:

ARES CREDIT STRATEGIES INSURANCE DEDICATED FUND SERIES INTERESTS OF THE SALI MULTI-SERIES FUND, L.P.

By: Ares Capital Management LLC, its investment manager

By: _____
Name:
Title:

LENDERS:

ACF FINCO I LP,
a Delaware limited partnership

By: _____
Name:
Title:

CION ARES DIVERSIFIED CREDIT FUND

By: _____
Name: Scott Lem
Title: Authorized Signatory

ARES CENTRE STREET PARTNERSHIP, L.P.,

By: Ares Centre Street GP, Inc., as general partner

By: _____
Name: Scott Lem
Title: Authorized Signatory

ARES CREDIT STRATEGIES INSURANCE DEDICATED FUND SERIES INTERESTS OF THE SALI MULTI-SERIES FUND, L.P.

By: Ares Capital Management LLC, its investment manager

By: _____
Name: Scott Lem
Title: Authorized Signatory

ARES COMMERCIAL FINANCE,

By: Ares Commercial Finance GP LP, its general partner
By: ACF GP LLC, its general partner

By: _____

Name: FRED BUBECK
Title: VICE PRESIDENT

AMENDMENT NO. 2 TO SECOND LIEN CREDIT AGREEMENT

This AMENDMENT NO. 2 TO SECOND LIEN CREDIT AGREEMENT, dated as of July 18, 2019 and effective as of June 29, 2019 (this "Amendment"), is by and among TELIGENT, INC., a Delaware corporation (the "Borrower"), its Subsidiaries signatory hereto as guarantors or hereafter designated as Guarantors pursuant to Section 8.11 of the Credit Agreement (as defined below), the lenders from time to time party hereto (each a "Lender" and, collectively, the "Lenders"), ARES CAPITAL CORPORATION, a Maryland corporation ("ARCC"), as administrative agent and collateral agent for the Lenders (in such capacity, together with its successors and assigns in such capacity, the "Administrative Agent"). For purposes of this Amendment, all terms used herein which are not otherwise defined herein, including but not limited to those terms used in the recitals hereto, shall have the respective meanings assigned thereto in the Amended Credit Agreement (as defined below).

WHEREAS, the Administrative Agent, Lenders, Borrower and other Credit Parties have entered into financing arrangements pursuant to which the Lenders (or Administrative Agent on behalf of the Lenders) have made and may make Loans and provide other financial accommodations to Borrower as set forth in (i) the Second Lien Credit Agreement, dated as of December 13, 2018, as amended by that certain Amendment No. 1 to Second Lien Credit Agreement, dated as of February 8, 2019 (as in effect prior to the effectiveness of this Amendment, the "Credit Agreement", and as the same is further amended by this Amendment and as may be further amended, restated, supplemented or otherwise modified from time to time, the "Amended Credit Agreement"), by and among the Administrative Agent, Lenders, Borrower and other Credit Parties and (ii) the other Credit Documents, including, without limitation, this Amendment;

WHEREAS, the Borrower, the Administrative Agent, and the Lenders desire to extend the DDTL A Commitment Expiration Date from June 30, 2019 to the first anniversary of the Closing Date without prior termination of the DDTL A Commitment; and

WHEREAS, the Borrower, the Administrative Agent, and the Lenders desire to amend certain provisions of the Credit Agreement, as provided more fully herein.

NOW THEREFORE, in consideration of the foregoing premises and the mutual agreements and covenants contained in the Credit Agreement and herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

Section 1. Amendments to the Credit Agreement. Subject to the conditions to effectiveness set forth in Section 3 hereof, and in reliance upon the representations and warranties made by the Credit Parties in Section 2 hereof, pursuant to Section 12.01 of the Credit Agreement and subject to the terms and conditions herein, the Credit Agreement is hereby amended as set forth below in this Section 1.

1.01. The defined term "DDTL A Commitment Expiration Date" set forth in Section 1.01 of the Credit Agreement is hereby deleted in its entirety and the following defined term is substituted therefor in its proper alphabetical order:

"'DDTL A Commitment Expiration Date' shall mean the date that is the first anniversary of the Closing Date."

Section 2. Representations and Warranties. Each Credit Party, jointly and severally, hereby represents and warrants to the Lenders and the Administrative Agent as follows, which representations and warranties are continuing and shall survive the execution and delivery hereof:

2.01. No Default. At and as of the date of this Amendment and both prior to and after giving effect to this Amendment, no Default or Event of Default is continuing.

2.02. Representations and Warranties True and Correct. At and as of the date of this Amendment and both prior to and after giving effect to this Amendment, each of the representations and warranties contained in the Credit Agreement and other Credit Documents is true and correct in all material respects (except where such representations and warranties expressly relate to an earlier date, in which case such representations and warranties are true and correct in all material respects as of such earlier date).

2.03. Corporate Power and Authority. Each Credit Party has the corporate or other organizational power and authority to execute and deliver this Amendment and carry out the terms and provisions of this Amendment and the Amended Credit Agreement and has taken all necessary corporate or other organizational action to authorize the execution, delivery and performance of this Amendment and the performance of the Amended Credit Agreement. Each Credit Party has duly executed and delivered this Amendment, and this Amendment and the Amended Credit Agreement constitute the valid and binding agreements of such Credit Party enforceable in accordance with their respective terms, subject to applicable bankruptcy, insolvency, fraudulent conveyance, moratorium, reorganization and other similar laws relating to or affecting creditors' rights generally and general principles of equity (whether considered in a proceeding in equity or law).

2.04. No Violation. The execution, delivery and performance by any Credit Party of this Amendment and the performance of the Amended Credit Agreement, and compliance with the terms and provisions thereof, will not (i) contravene any applicable provision of any material Applicable Law of any Governmental Authority, (ii) result in any breach of any of the terms, covenants, conditions or provisions of, or constitute a default under, or result in the creation or imposition of (or the obligation to create or impose) any Lien upon any of the property or assets of any Credit Party (other than Permitted Liens and Liens created under the Credit Documents) pursuant to (A) the terms of any material indenture, loan agreement, lease agreement, mortgage or deed of trust, or (B) any other Material Contracts Obligation, in the case of either clause (ii)(A) or (ii)(B), to which any Credit Party is a party or by which it or any of its property or assets is bound, or (iii) violate any provision of the Organization Documents of any Credit Party, except with respect to any conflict, breach or contravention or default (but not creation of Liens) referred to in clause (ii), to the extent that such conflict, breach, contravention or default could not reasonably be expected to have a Material Adverse Effect.

Section 3. Conditions. This Amendment shall not become effective until each of the following conditions is satisfied (or waived by the Required Lenders):

3.01. The Administrative Agent shall have received counterparts of this Amendment duly executed by each Credit Party and each other relevant party to this Amendment;

3.02. The representations and warranties contained in Section 2 hereof shall be true and correct in all material respects on and as of the date hereof, as though made on such date (except to the extent that such representations and warranties relate solely to an earlier date, in which case such representations and warranties shall be true and correct in all material respects on and as of such earlier date);

3.03. The Administrative Agent shall have received, for its own account, the fees, costs and expenses due and payable to it pursuant to Section 4.01 hereof and Section 12.05 of the Amended Credit Agreement (including the reasonable fees, disbursements and other charges of counsel) for which invoices have been presented prior to the date hereof; and

3.04. The Administrative Agent shall have received fully executed copies of Amendment No. 1 to the Intercreditor Agreement in form and substance acceptable to the Administrative Agent.

Section 4. Miscellaneous.

4.01. Fees and Expenses. The Borrower agrees and acknowledges that all reasonable and documented out-of-pocket costs and expenses incurred by the Administrative Agent in connection with this Amendment, including the reasonable fees, disbursements and other charges of one counsel, shall be paid by the Credit Parties to the Administrative Agent.

4.02. No Waiver or Modification. Nothing contained herein shall be deemed to constitute a waiver of compliance with any term or condition contained in the Credit Agreement or any other Credit Document or constitute a course of conduct or dealing among the parties. The Administrative Agent and Lenders reserve all rights, privileges and remedies under the Credit Documents. Except as expressly amended hereby, the Credit Agreement and other Credit Documents remain unmodified and in full force and effect in accordance with their respective terms and are hereby ratified and confirmed in all respects.

4.03. Credit Document. This Amendment shall constitute a Credit Document under and as defined in the Amended Credit Agreement. All references in the Credit Documents to the Credit Agreement shall be deemed to be references to the Credit Agreement as amended hereby.

4.04. Governing Law. THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND ANY CLAIM, CONTROVERSY OR DISPUTE UNDER, ARISING OUT OF OR RELATING TO THIS AMENDMENT, WHETHER BASED IN CONTRACT (AT LAW OR IN EQUITY), TORT OR ANY OTHER THEORY, SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

4.05. Counterparts. This Amendment may be executed by one or more of the parties hereto in any number of separate counterparts, each of which when so executed and delivered shall be deemed an original, but all such counterparts together shall constitute but one and the same instrument. Delivery of an executed counterpart of a signature page of this Amendment by facsimile or in electronic format (i.e., "pdf" or "tif") by electronic transmission shall be effective as delivery of a manually executed counterpart of this Amendment.

4.06. Headings. Section headings in this Amendment are included herein for convenience of reference only and shall not affect the interpretation of this Amendment.

4.07. Binding Effect; Assignment. This Amendment shall be binding upon and inure to the benefit of the Borrower, the other Credit Parties, the Administrative Agent and the Lenders and their respective successors and assigns in accordance with the terms of the Credit Agreement.

4.08. Integration. This Amendment, the Amended Credit Agreement, and the other Credit Documents incorporate all negotiations of the parties hereto with respect to the subject matter hereof and thereof and are the final expression and agreement of the parties hereto and thereto with respect to the subject matter hereof and thereof. This Amendment, the Amended Credit Agreement, and the other Credit Documents represent the agreement of the parties hereto with respect to the subject matter hereof and thereof, and there are no promises, undertakings, representations or warranties by any party hereto or thereto relative to the subject matter hereof or thereof not expressly set forth or referred to herein or therein.

4.09. Reaffirmation. Each Credit Party as debtor, grantor, pledgor, guarantor, assignor, or in any other similar capacity in which such Credit Party grants liens or security interests in its property or otherwise acts as accommodation party or guarantor, as the case may be, hereby (i) ratifies and reaffirms all of its payment and performance obligations, contingent or otherwise, under each Credit Document to which it is a party (after giving effect hereto) and (ii) to the extent such Credit Party granted liens on or security interests in any of its property pursuant to any such Credit Document as security for or otherwise guaranteed the Borrower's Obligations under or with respect to the Credit Documents, ratifies and reaffirms such guarantee and grant of security interests and liens and confirms and agrees that such security interests and liens hereafter secure all of the Obligations as amended hereby.

[Remainder of the page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their respective officers thereunto duly authorized, as of the date first above written.

BORROWER:

TELIGENT, INC.

By: _____
Name: Damian Finio
Title: CFO

GUARANTORS

IGEN, INC.

By: _____
Name: Damian Finio
Title: CFO

TELIGENT PHARMA, INC.

By: _____
Name: Damian Finio
Title: CFO

ADMINISTRATIVE AGENT AND A LENDER: **ARES CAPITAL CORPORATION,**
a Maryland corporation

By: _____
Name: Scott Lem
Title: Authorized Signatory

[Signature Page to Amendment No. 2 to Credit Agreement]

LENDERS:

ACF FINCO I LP,
a Delaware limited partnership

By: _____
Name: Olek Szczypak
Title: Authorized Signer

CION ARES DIVERSIFIED CREDIT FUND

By: _____
Name:
Title:

ARES CENTRE STREET PARTNERSHIP, L.P.,

By: Ares Centre Street GP, Inc., as general partner

By: _____
Name:
Title:

ARES CREDIT STRATEGIES INSURANCE DEDICATED FUND SERIES INTERESTS OF THE SALI MULTI-SERIES FUND, L.P.

By: Ares Capital Management LLC, its investment manager

By: _____
Name:
Title:

LENDERS:

ACF FINCO I LP,
a Delaware limited partnership

By: _____
Name:
Title:

CION ARES DIVERSIFIED CREDIT FUND

By: _____
Name: Scott Lem
Title: Authorized Signatory

ARES CENTRE STREET PARTNERSHIP, L.P.,

By: Ares Centre Street GP, Inc., as general partner

By: _____
Name: Scott Lem
Title: Authorized Signatory

ARES CREDIT STRATEGIES INSURANCE DEDICATED FUND SERIES INTERESTS OF THE SALI MULTI-SERIES FUND, L.P.

By: Ares Capital Management LLC, its investment manager

By: _____
Name: Scott Lem
Title: Authorized Signatory

ARES COMMERCIAL FINANCE,

By: Ares Commercial Finance GP LP, its general partner
By: ACF GP LLC, its general partner

By: _____

Name: Olek Zecevpak
Title: Authorized Signer

[Signature Page to Amendment No. 2 to Credit Agreement]

February 5, 2020

Jason Grenfell-Gardner
c/o Ms. Elizabeth Zuckerman, Esq.
Mason, Griffin & Pierson, P.C.
101 Poor Farm Road
Princeton, NJ 08540

Dear Jason:

The purpose of this letter agreement ("Agreement and Release") is to confirm your separation of employment with Teligent, Inc. ("Teligent" or the "Company") and to set forth the terms of your separation from employment pursuant to your July 30, 2012, "Employment Agreement" with IGI Laboratories, Inc. (subsequently renamed Teligent, Inc.).

1. STANDARD SEPARATION PROVISIONS FOLLOWING TERMINATION OF EMPLOYMENT

a. Your last date of employment with the Company was February 4, 2020 (the "Separation Date").

b. On the first practicable payroll date following the Separation Date, you will receive a lump-sum payment, less applicable withholdings and deductions, for the value of the unused vacation time you have accrued and to which you are entitled under the Company's vacation policy.

c. In lieu of written notice pursuant to Section 8.1 of your Employment Agreement, the Company agrees to pay you an amount equal to $1,831.00

d. The Company will pay you the annual bonus you earned for 2019 on the date that annual bonuses are paid to Company employees in the amount of $82,000

e. You will be given the opportunity to purchase the Medical and Dental Plan coverage for which you are eligible through the Consolidated Omnibus Reconciliation Act (COBRA) for a period of up to 18 months at your own expense. You will receive the appropriate COBRA application form and information regarding rates and period of coverage in the near future. Please note that at the end of the month within which the Separation Date occurs, your current coverage will be terminated. However, upon the completion and processing of your COBRA application, coverage will be retroactively reinstated.

f. Your Group Life/Accidental Death and Dismemberment, Short Term and Long-Term Disability coverages will terminate on the Separation Date. Your Life Insurance coverage may be converted to an individual policy within 31 days from your coverage termination date by making written application to Guardian. You have 31 days from your termination date to

exercise the conversion feature. A copy of the form and life conversation rates are attached to this form for your convenience.

g. You will be provided with information describing your options under the Teligent 401K Savings Plan under separate cover.

h. Other than as set forth in sub-Paragraphs a. through f. above, the Company shall have no other financial obligations to you under any compensation or benefit plan, program or policy and your participation in the Company compensation and benefit plans, programs and policies shall cease as of the date of your termination.

i. If the Company receives requests for references from prospective employers, it will provide only dates of employment and positions held.

j. The Company agrees not to contest any claims for unemployment insurance benefits made by you.

k. You must return to the Company all Company property, including all notes, reports, plans, keys, security cards and/or identification cards, customer lists, product information and other documents and property including computer equipment, and cellular phones that were created, developed, generated or received by you during your employment or that are the property of the Company, whether or not such items are confidential to the Company. You will also be responsible for discharging your obligations under Section 8.3 of the Employment Agreement.

l. You are reminded of your continuing legal and contractual obligations, including without limitation those set forth in your Employment Agreement, not to use or disclose any secret, confidential, or proprietary information or documents of the Company for any purpose following the termination of your employment with the Company. Specifically, you are not to disclose, nor use for your benefit or the benefit of any other person or entity, any information received from Teligent or its parent, subsidiaries or affiliated companies (individually or collectively a "Teligent Company"), which is confidential or proprietary and: (i) which has not been disclosed publicly by a Teligent Company; (ii) which is otherwise not a matter of public knowledge; or (iii) which is a matter of public knowledge but you knows or have reason to know that such information became a matter of public knowledge through an unauthorized disclosure. Proprietary or confidential information includes information the unauthorized disclosure or use of which would reduce the value of such information to the Company. Such information includes, without limitation, any Company customer and supplier lists, trade secrets, intellectual property, confidential information about (or provided by) any customer or prospective or former customer or business partner of the Company, information concerning the Company's business or financial affairs (including its books and records, commitments, procedures, plans, strategies, inventions, and prospects), products developed or in development by the Company, securities positions, or current or prospective transactions or business of the Company.

2. SEPARATION BENEFITS

a. You will receive the compensation associated with a "Termination of Employment Without Cause" in the manner outlined in your Employment Agreement in the first paragraph of Section 8.1 and Section 8.4 (which requires you to execute a release of liability to receive such compensation). Specifically, (i) the Company will pay you an amount equal to one-twelfth of your annual base salary at the rate in effect as of the Separation Date for a period of 6 months commencing on the Company's first practicable payroll date following the Effective Date, (ii) you will receive one-twelfth of the annual bonus that would have been paid to you for 2020, payable when bonuses are paid to similarly situated employees of the Company for fiscal year 2020, (iii) all of your unvested equity based awards shall vest, and (iv) pursuant to the terms of the retention bonus letter, the Company will pay you an amount equal to $82,045, less required withholdings, in July 2020. By signing this letter, thereby agreeing to the Release in Paragraph 3 below, you will fulfill your obligations under Employment Agreement Section 8.4.

b. You expressly agree that you shall be responsible for remitting to federal, state and/or local tax authorities your share of any applicable taxes due from the payments set forth in this Agreement and Release, to the extent that such taxes have not been withheld from said payments and remitted on your behalf, and shall hold the Company harmless and indemnify it for any liability, costs and expenses (including attorney's fees arising from your failure to remit your share of any applicable taxes), caused by any tax authority relating in any way to the tax treatment of the payment made pursuant to this Agreement and Release.

3. RELEASE AND WAIVER OF RIGHTS

In exchange for the consideration described in Section 8.1 of the Employment Agreement and in Paragraph 2 above you agree as follows:

a. to release and forever discharge the Company, its subsidiaries and affiliates and their parent organizations, predecessors, successors, officers, directors, employees, agents, attorneys, associates and employee benefit plans from all claims, demands or causes of action arising out of facts or occurrences prior to the date of this Agreement and Release, whether known or unknown to you. You agree that this release of claims is intended to be broadly construed so as to resolve any pending and potential disputes between you and the Company that you have up to the date you sign this Release, whether such disputes are known or unknown to you, including, but not limited to, claims based on express or implied contract; any action arising in tort, including, but not limited to libel, slander, defamation, intentional infliction of emotional distress, or negligence; any or all claims for wrongful discharge; Title VII of the Civil Rights Act of 1964 as amended; the Civil Rights Acts of 1866 and 1871; the Employee Retirement Income Security Act; the Family and Medical Leave Act, the Americans With Disabilities Act; the Occupational Safety and Health Act; the Immigration Reform and Control Act; the Fair Labor Standards Act of 1938 as amended; the Occupational Safety and Health Act; Section 806 of the Sarbanes-Oxley Act of 2002, the New Jersey Law Against Discrimination – N.J. Rev. Stat. §10:5-1 et seq.; New Jersey Statutory Provision Regarding Retaliation/Discrimination for Filing a Workers' Compensation Claim – N.J. Rev. Stat. §34:15-39.1 et seq.; New Jersey Family Leave Act – N.J. Rev. Stat. §34:11B-1 et seq.; New Jersey Smokers' Rights Law – N.J. Rev. Stat. §34:6B-1 et seq.; New Jersey Equal Pay Act – N.J. Rev. Stat. §34:11-56.1 et seq.; New Jersey Genetic Privacy Act – N.J. Rev. Stat. Title 10, Ch. 5, §10:5-43 et seq.; New Jersey Conscientious Employee Protection Act (Whistleblower Protection) – N.J. Stat. Ann. §34:19-3 et seq.; New

Jersey Wage Payment and Work Hour Laws; New Jersey Public Employees' Occupational Safety and Health Act – N.J. Stat. Ann. §34:6A-25 et seq.; New Jersey Fair Credit Reporting Act; the Millville Dallas Automotive Plant Job Loss Notification (mini-WARN) Act; New Jersey Fair Credit Reporting Act; New Jersey False Claims Act; New Jersey Civil Rights Act; New Jersey mini-COBRA; New Jersey laws regarding Political Activities of Employees, Lie Detector Tests, Jury Duty, Employment Protection, and Discrimination; and other applicable federal, state or local law, regulation, ordinance or order, and including all claims for, or entitlement to, attorneys' fees. However, the foregoing release is not intended to cover any claim for vested benefits to which you are entitled, if any, under the Company's Pension and Investment Savings Plan.

b. You affirm that you have not filed or caused to be filed, and currently are not a party to any claim, complaint, or action against the Company in any forum or form. You further affirm that you have been paid and/or have received all leave (paid or unpaid), compensation, wages, bonuses, commissions, and/or benefits to which you may be entitled and that no other leave (paid or unpaid), compensation, wages, bonuses, commissions and/or benefits are due to you, except as described in this Agreement and Release. You further affirm that you have no known workplace injuries or occupational diseases and have been provided and/or have not been denied any leave requested under any applicable family and medical leave laws.

c. If you challenge the enforceability of this Agreement and Release in a court of law or before any administrative agency, or you breach your obligations under the Agreement and Release, except as provided in Paragraph 6, you acknowledge that (i) you will reimburse the Company for any monetary consideration previously received by you under this Agreement and Release, and (ii) you agree to pay reasonable attorneys' fees and costs incurred by the Company to the extent the Company successfully enforces the Agreement and Release or proves a breach of the Agreement and Release.

4. NO NEGATIVE STATEMENTS

a. In further consideration of this Agreement and Release, you agree to refrain from any publication or any type of communication, oral or written, of a defamatory or disparaging statement pertaining to the Company, its corporate parent(s) and affiliates, or their respective past, present and future officers, agents, directors, supervisors, employees or representatives, except as otherwise required by law. The Company shall not make any formal statement containing any disparaging remarks about you or otherwise take any action that could reasonably be anticipated to cause damage to your reputation, or otherwise make remarks that may reflect negatively upon you. Notwithstanding the foregoing provision, you and the Company may testify truthfully pursuant to compulsory process. The Company shall direct John Celentano and James Gale not to make statements containing any disparaging remarks about you or otherwise take any action that could reasonably be anticipated to cause damage to your reputation, or otherwise make remarks that may reflect negatively upon you. The breach of this paragraph shall not affect the continuing validity or enforceability of this Agreement and Release. Inquiries about your employment at Teligent should be directed to Damian Finio, Chief Financial Officer, and the Company will respond to inquiries by only providing your dates of service, title, and final compensation.

5. NO ADMISSION OF LIABILITY

a. This Agreement and Release shall not be construed as an admission by the Company of any wrongdoing or any violation of federal, state or local law, and the Company specifically disclaims any wrongdoing against, or liability to you.

6. YOU ACKNOWLEDGE AND AGREE AS FOLLOWS:

a. the payments and other benefits to be provided to you under Section 8.1 of the Employment Agreement are specifically conditioned upon your execution of this Agreement and Release;

b. you acknowledge that, before signing this Agreement and Release, you were given a period of at least 21 calendar days to consider this Agreement and Release;

c. you waive any right you might have to additional time beyond this 21 day consideration period within which to consider this Agreement and Release;

d. you have read and understand this Agreement and Release in its entirety;

e. you have been advised by the Company to consult with an attorney (at your own expense) before signing this Agreement and Release and this paragraph constitutes such advice in writing;

f. you are waiving, among other things, any age discrimination claims under the Age Discrimination in Employment Act ("ADEA"), provided, however, you are not waiving any claims under the ADEA that may arise out of acts or omissions done or occurring after the date this Agreement is executed;

g. You may revoke this Agreement and Release within seven days after your execution of it, and it shall not become effective until the expiration of such seven-day revocation period. Any revocation within this period must be submitted, in writing, to Teligent Human Resources and state, "I hereby revoke my acceptance of our Agreement and Release." The revocation must be delivered to Damian Finio, Chief Financial Officer, 33 Wood Avenue South, Iselin, NJ 08830 and postmarked within seven (7) calendar days of your execution of this Agreement and Release. If the last day of the revocation period is a Saturday, Sunday, or legal holiday in the state in which you reside, then the revocation period shall not expire until the next following day which is not a Saturday, Sunday, or legal holiday. In the event of a timely revocation by you, this Agreement and Release will be deemed null and void and the Company will have no obligations hereunder. This Agreement and Release will become effective on the eighth (8th) day after you have signed it, provided that you have not revoked it (such date, the "Effective Date").

h. You enter into this Agreement and Release knowingly and voluntarily, without duress or reservation of any kind, and after having given the matter full and careful consideration; and

i. Nothing in this Agreement and Release shall prevent any Party from asserting any claim to enforce the terms of this Agreement or to seek a judicial determination of the validity of the waiver of ADEA claims.

7. NON-WAIVER

j. Nothing in this Agreement and Release limits your ability to file a charge or complaint with the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission (each a "Government Agency"). Your further understands that this Agreement and Release does not limit your ability to communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. However, to the maximum extent permitted by law, you agree that if such a charge or complaint is made, you shall not be entitled to recover any individual monetary relief or other individual remedies. This Agreement and Release does not limit or prohibit your right to receive an award for information provided to any Government Agency to the extent that such limitation or prohibition is a violation of law.

8. INDEMNIFICATION

a. The Company will indemnify you in accordance with the terms of the Company's articles of incorporation and/or by-laws. You shall be covered under any directors' and officers' liability insurance policy in effect for the Company or any of its affiliates as to which you served as a director or officer.

9. MISCELLANEOUS

k. This Agreement and Release contains the entire agreement between you and the Company concerning your separation from employment. Your post-separation obligations to the Company contained in your Employment Agreement will remain in full force and effect.

l. This Agreement and Release shall be construed and enforced in accordance with New Jersey law, to the extent not governed by federal law.

m. In the event any portion of this Agreement and Release is deemed to be invalid or unenforceable, that portion will be deemed omitted and the remainder of this Agreement and Release will remain in full force and effect.

n. This Agreement and Release may be executed in two or more counterparts, each of which shall be an original and all of which together shall constitute one and the same instrument.

If you agree to the terms set forth above, please sign the below and return the signed Agreement and Release to Damian Finio, Chief Financial Officer of the Company.

Teligent, Inc.

By: _____ March 3, 2020

PLEASE READ THE FOREGOING AGREEMENT CAREFULLY BEFORE SIGNING. THIS AGREEMENT INCLUDES A RELEASE OF ALL CLAIMS, WHETHER KNOWN OR UNKNOWN, YOU MAY HAVE IN CONNECTION WITH YOUR EMPLOYMENT WITH THE COMPANY INCLUDING, BUT NOT LIMITED TO, YOUR SEPARATION THEREFROM.

_____
Jason Grenfell-Gardner
Dated: March 3rd, 2020

Exhibit 21

List of Subsidiaries

Subsidiary	**Jurisdiction of Formation**
Igen, Inc.	Delaware
Teligent Pharma, Inc.	Delaware
Teligent Luxembourg S.a.r.l.	Luxembourg
Teligent OÜ	Luxembourg
Teligent Canada, Inc.	British Columbia, Canada
Microburst Energy, Inc. (Inactive)	Delaware
Blood Cells, Inc. (Inactive)	Delaware
Flavorsome, Ltd. (Inactive)	Delaware
Teligent Jersey Limited (dissolved 2/17/2020)	Jersey (U.K.)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-224188, 333-27173, 333-47006, 333-61716, 333-163524, 333- 171446, 333-173615, 333-173148, 333-187221 and 333-196543) and Form S-8 (Nos. 33-58479, 333- 28183, 33-65249, 333-52312, 333-65553, 333-67565, 333-79333, 333-79341, 333-160341, 333-160342, 333-160865, 333-167387 and 333-197811) of our report dated April 13, 2020, relating to the consolidated financial statements of Teligent, Inc. and subsidiaries (the "Company") appearing in the Annual Report on Form 10-K of the Company for the year ended December 31, 2019.

/s/ DELOITTE & TOUCHE LLP

Parsippany, NJ
April 13, 2020

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Timothy B. Sawyer, certify that:

1. I have reviewed this annual report on Form 10-K of Teligent, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: April 13, 2020

/s/ Timothy B. Sawyer

President and Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Damian Finio, certify that:

1. I have reviewed this annual report on Form 10-K of Teligent, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 13, 2020

/s/ Damian Finio

Principal Financial Officer, Principal Accounting Officer

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Teligent, Inc., a Delaware corporation (the "**Company**"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2019 (the "**Form 10-K**") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 13, 2020

/s/ Timothy B. Sawyer

President and Chief Executive Officer

Dated: April 13, 2020

/s/ Damian Finio

Principal Financial Officer, Principal Accounting Officer