Teligent, Inc.
Form 10-Q
December 12, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q
(Mark One)

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

For the quarterly period ended September 30, 2018

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

organization)

105 Lincoln Avenue	
Buena, New Jersey	**08310**
(Address of Principal Executive Offices)	*(Zip Code)*

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

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 þ No ¨

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes þ No ¨

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

Large accelerated filer	¨	Accelerated filer	þ
Non-accelerated filer	¨	Smaller reporting company	¨

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 þ

The number of shares outstanding of the issuer's common stock is 53,774,221 shares as of December 10, 2018.

OTHER INFORMATION

When used in this report, the terms, “we,” the “Company,” “our,” and “us” refer to Teligent, Inc., a Delaware corporation (formerly IGI Laboratories, Inc.), and its consolidated subsidiaries.

PART I
FINANCIAL INFORMATION
ITEM 1. Financial Statements
TELIGENT, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share information)
(Unaudited)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,267	$ 26,692
Accounts receivable, net of allowance for doubtful accounts of $2,787 and $2,185, as of September 30, 2018 and December 31, 2017, respectively	16,707	12,742
Inventories, net	17,882	16,075
Prepaid expenses and other receivables	1,522	3,622
Total current assets	51,378	59,131
Property, plant and equipment, net	88,387	68,355
Intangible assets, net	52,045	56,017
Goodwill	464	471
Other assets	608	611
Total assets	$ 192,882	$ 184,585
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,476	$ 10,595
Accrued expenses	10,437	8,101
Term Loan, net of debt discount and debt issuance costs (face of $25,000 as of September 30, 2018)	24,168	—
Total current liabilities	39,081	18,696
Convertible 3.75%	61,634	120,977

Senior Notes, net of debt discount and debt issuance costs (face of $68,660 and $143,750 as of September 30, 2018 and December 31, 2017, respectively)				
Convertible 4.75% Senior Notes, net of debt discount and debt issuance costs (face of $75,090 as of September 30, 2018)	56,148		—	
Deferred tax liability	249		159	
Other long term liabilities	70		—	
Total liabilities	157,182		139,832	
Commitments and Contingencies				
Stockholders’ equity:				
Common stock, $0.01 par value, 100,000,000 shares authorized; 53,762,888 and 53,400,281 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	557		554	
Additional paid-in capital	119,346		106,312	
Accumulated deficit	(81,960)		(60,094)	
Accumulated other comprehensive loss	(2,243)		(2,019)	
Total stockholders’ equity	35,700		44,753	
Total liabilities and stockholders' equity	$	192,882	$	184,585

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

TELIGENT, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except shares and per share information)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenue, net	$ 18,294	$ 11,340	$ 49,088	$ 45,435
Costs and expenses:				
Cost of revenues	11,575	8,802	32,365	23,926
Selling, general and administrative expenses	4,845	5,971	15,932	14,976
Product development and research expenses	3,087	4,606	10,445	13,387
Total costs and expenses	19,507	19,379	58,742	52,289
Operating loss	(1,213)	(8,039)	(9,654)	(6,854)
Other income (expense):				
Foreign currency exchange (loss) gain	(176)	1,744	(2,071)	6,645
Partial extinguishment of Convertible 3.75% Senior Notes	—	—	(2,467)	—
Interest and other expense, net	(2,693)	(2,663)	(7,764)	(8,731)
Loss before income tax expense	(4,082)	(8,958)	(21,956)	(8,940)
Income tax (benefit) expense	(137)	24	(90)	130
Net loss attributable to common	$ (3,945)	$ (8,982)	$ (21,866)	$ (9,070)

shareholders				
Basic and diluted loss per share	$ (0.07)	$ (0.17)	$ (0.41)	$ (0.17)
Weighted average shares of common stock outstanding:				
Basic and diluted shares	53,625,768	53,391,948	53,532,277	53,297,889

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

TELIGENT, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2018	**2017**	**2018**	**2017**
Net loss	$ (3,945)	$ (8,982)	$ (21,866)	$ (9,070)
Other comprehensive income (loss), net of tax;				
Foreign currency translation adjustment	108	378	(224)	133
Other comprehensive income (loss)	108	378	(224)	133
Comprehensive loss	$ (3,837)	$ (8,604)	$ (22,090)	$ (8,937)

The accompanying notes are an integral part of the condensed consolidated financial statements.
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TELIGENT, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share information)
(Unaudited)

	Common Stock		Additional	Accumulated Other		Total	
	Shares	Amount	Paid-In Capital	Comprehensive Loss	Deficit	Accumulated Equity	Stockholders'
Balance, December 31, 2017	53,490,281	$ 554	$ 106,312	$ (2,019)	$ (60,094)	$ 44,753	
Stock based compensation expense	—	—	1,654	—	—	1,654	
Stock options exercised	236,200		244	—	—	246	
Issuance of stock for vested restricted stock units	101,607		(1)	—	—	—	
Issuance of stock to a consultant	25,000		102			102	
Fair value of conversion feature on Convertible 4.75% Senior Notes	—	—	18,637	—	—	18,637	
Partial extinguishment of equity component of Convertible 3.75% Senior Notes	—	—	(7,602)	—	—	(7,602)	
Cumulative	—	—	—	(224)	—	(224)	

translation adjustment								
Net loss	—	—	—	—		(21,866)	(21,866)	
Balance, September 30, 2018	53,75	$2,888	557	$ 119,346	$ (2,243)	$ (81,960)	$	35,700

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

TELIGENT, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Nine months ended September 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (21,866)	$ (9,070)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization of fixed assets	1,703	1,264
Provision for bad debt expense	601	1,738
Provision for write down of inventory	844	1,489
Issuance of stock to consultant	102	—
Stock based compensation	1,572	2,427
Amortization of debt issuance costs	727	695
Amortization of intangible assets	2,302	2,143
Foreign currency exchange loss (gain)	2,071	(6,645)
Partial extinguishment of Convertible 3.75% Senior Notes	2,467	—
Amortization of debt discount	6,353	6,376
Gain on sale of fixed assets	(20)	—
Loss on impairment of	22	113

intangible assets		
Changes in operating assets and liabilities:		
Accounts receivable	(4,587)	(2,491)
Inventories	(2,746)	(2,767)
Prepaid expenses and other current receivables	2,081	510
Other assets	4	21
Accounts payable and accrued expenses	(6,944)	1,537
Net cash used in operating activities	(15,314)	(2,660)
Cash flows from investing activities:		
Capital expenditures	(18,315)	(26,002)
Proceeds from sale of fixed assets	38	—
Net cash used in investing activities	(18,277)	(26,002)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	246	269
Proceeds from 2021 Term Loan	25,000	—
Debt fees on Convertible 4.75% Senior Notes and 2021 Term Loan	(2,539)	—
Net cash provided by	22,707	269

financing activities		
Effect of exchange rate on cash and cash equivalents	(542)	618
Net decrease in cash, cash equivalents and restricted cash	(10,884)	(28,393)
Cash, cash equivalents and restricted cash at beginning of period	27,165	66,481
Cash, cash equivalents and restricted cash at end of period	$ 15,739	$ 38,706
Supplemental Cash flow information:		
Cash payments for interest	$ 3,136	$ 2,695
Cash payments for income taxes	66	102
Non-cash operating, investing and financing transactions:		

Issuance of stock to a consultant	102	—
Acquisition of capital expenditures in accounts payable and accrued expenses	1,316	5,029
Capitalized interest in capital expenditures	2,013	1,058
Capitalized stock compensation in capital expenditures	82	101

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

TELIGENT, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 8-03 of Regulation S-X. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, as updated by other reports we may file from time to time with the Securities and Exchange Commission ("SEC"). The condensed consolidated balance sheet as of December 31, 2017 has been derived from those audited consolidated financial statements. Operating results for the nine-month period ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

1.Correction to Previously Issued Unaudited Interim Condensed Consolidated Financial Statements

Subsequent to the issuance of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, management determined adjustments were needed to correct the presentation of certain errors in the Company's previously reported unaudited condensed consolidated financial statements as of and for the three and nine-months ended September 30, 2017. Accordingly, the accompanying Condensed Consolidated Statement of Operations of the Company for the three and nine-months ended September 30, 2017, and the related notes hereto, have been revised to correct these errors (the "Revision"). A summary of the correction of these errors, and their impact on the accompanying Condensed Consolidated Statement of Operations for the three and nine-months ended September 30, 2017 are, as follows:

(1) The Company pays wholesalers certain fees associated with the sale of the Company's product. The payment of these fees had been historically classified by the Company as cost of revenues and accrued expenses prior to the adoption of ASC 606, *Revenue from Contracts with Customers.* As disclosed in Note 4, the Company adopted ASC 606 on January 1, 2018 using the modified retrospective method, at which time the Company began classifying the payment of wholesaler fees as a reduction of revenue and accounts receivable. Upon further analysis, however, management determined that these fees should have always been classified as a reduction of revenue and accounts receivable, rather than as costs of revenues and accrued expenses, because the services provided by the Company's wholesalers cannot generally be provided by third parties and the underlying fees are not specifically identifiable from other services. As a result, the accompanying Condensed Consolidated Statement of Operations for the three and nine-months ended September 30, 2017 has been revised to correct the presentation of wholesaler fees as a reduction of revenue rather than as cost of revenues. The correction of this error resulted in a reduction of revenue of approximately $1.5 million and $5.7 million, respectively, for the three and nine-month periods ended September 30, 2017. In addition, the correction of this error resulted in a reduction in accounts receivable and decrease in accrued expenses of approximately $6.1 million, respectively, as of September 30, 2017 and $7.0 million, respectively, as of December 31, 2017.

(2) Prior to the adoption of ASC 606, the Company classified Medicaid, Medicare and other rebates (the "Rebates") as a reduction of accounts receivable, whereas subsequent to adoption of ASC 606 the Company began classifying the Rebates as accrued expenses. Upon further analysis, management determined that the Rebates should have always been classified as accrued expenses because their terms require cash settlement and are payable to third parties that are other than the Company's customer. The correction of this error resulted in an increase in accounts receivable and increase in accrued expenses of $2.3 million, respectively, as of September 30, 2017 and $1.6 million, respectively, as of December 31, 2017.

The following tables summarize the effects of the Revision on the Company's unaudited interim condensed consolidated financial statements as of and for the three and nine-months ended September 30, 2017 (in thousands):

Condensed Consolidated Statements of Operations

	Three Months Ended September 30, 2017			**Nine Months Ended September 30, 2017**		
	As Previously Reported	**Adjustment**	**As Revised**	**As Previously Reported**	**Adjustment**	**As Revised**
Revenue, net	12,851	1,511 (1)	11,340	51,150	5,715 (1)	45,435

Cost of revenues	10,3131,511	(1)	8,802	29,641	5,715	(1) 23,926
Total costs and expenses	20,8901,511	(1)	19,379	58,004	5,715	(1) 52,289

	Condensed Consolidated Balance Sheet September 30, 2017				Condensed Consolidated Balance Sheet December 31, 2017			
	As Previously Reported	Adjustment		As Revised	As Previously Reported	Adjustment		As Revised
Accounts receivable, net	25,026	3,800	(1),(2)	21,226	18,143	5,401	(1),(2)	12,742
Total current assets	79,846	3,800	(1),(2)	76,046	64,532	5,401	(1),(2)	59,131
Total assets	194,466	3,800	(1),(2)	190,666	189,986	5,401	(1),(2)	184,585
Accrued expenses	16,372	3,800	(1),(2)	12,572	13,502	5,401	(1),(2)	8,101
Total current liabilities	25,237	3,800	(1),(2)	21,437	24,097	5,401	(1),(2)	18,696
Total liabilities	143,939	3,800	(1),(2)	140,139	145,233	5,401	(1),(2)	139,832
Total liabilities and stockholders' equity	194,466	3,800	(1),(2)	190,666	189,986	5,401	(1),(2)	184,585

	Condensed Consolidated Statement of Cash Flows Nine Months Ended September 30, 2017			
	As Previously Reported	Adjustment		As Revised
Cash flows from operating activities				
Accounts receivable	(4,960)	(2,469)	(1),(2)	(2,491)
Accounts payable and accrued expenses	4,006	2,469	(1),(2)	1,537

2. Nature of the Business and Liquidity

Nature of the Business

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 in alternate dosage forms. 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 32 generic topical pharmaceutical products and four branded generic injectable pharmaceutical products. In Canada, we sell over 30 generic and branded generic injectable products and medical devices. Generic pharmaceutical products are bioequivalent to their brand name counterparts. We also provide contract manufacturing services to the pharmaceutical, over-the-counter ("OTC"), and cosmetic markets. We operate our business under one reportable segment. Our common stock is traded on the NASDAQ Global Select Market under the trading symbol “TLGT.” Our principal executive office, laboratories and manufacturing facilities are located at 105 Lincoln Avenue, Buena, New Jersey. We have additional offices located in Iselin, New Jersey, Toronto, Canada, and Tallinn, Estonia.

Liquidity

Our capital resources were comprised of cash and cash equivalents of $15.3 million and $26.7 million as of September 30, 2018 and December 31, 2017, respectively. The reduction in our cash during the nine months ended September 30, 2018 was largely due to our additional year-to-date investment of $18.3 million in the Company's new manufacturing facility located in Buena, New Jersey, along with the timing of our accounts receivable collections and expense payments associated with our launch of six new products in the U.S. market. In addition, we had an accumulated deficit of $82.0 million as of September 30, 2018, and incurred a $21.9 million net loss and used $15.3 million in net cash from operating activities during the nine months ended September 30, 2018.

Our liquidity needs have typically arisen from the funding of our new manufacturing facility, product manufacturing costs, research and development programs and the launch of new products. In the past, we have met these cash requirements through cash inflows from operations, working capital management, and proceeds from borrowings such as our Convertible Senior Notes and Term Loan discussed in Note 7. We expect to continue to incur significant expenditures for the development of new products in our pipeline, and the manufacturing and sales and marketing of our existing product. While we rely heavily on cash flows from operating activities and borrowings from outside sources to execute our operational strategy and meet our financial commitments and other short-term financial needs, we cannot be certain that sufficient capital will be generated through operations or will be available to the Company to the extent required and on acceptable terms.

In addition, were unable to file our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 with the SEC by the required filing date. As a result, the Company was not in compliance with a non-financial covenant prescribed by our Term Loan, which requires timely filing of our annual and interim consolidated financial statements, and our ability to offer up to $50.0 million in debt or equity securities through our existing shelf registration statement on file with the SEC was suspended for a period of twelve months. Moreover, due to the lack of compliance with the non-financial covenant prescribed by our Term Loan, we reclassified the net carrying value of $24.2 million as current debt in the accompanying Condensed Consolidated Balance Sheet as of September 30, 2018.

The foregoing matters, when considered in the aggregate, raise substantial doubt about the Company’s ability to continue as a going concern. However, the accompanying Condensed Consolidated Financial Statements do not include any adjustments that might result from the outcome of this uncertainty. Notwithstanding these matters, we continue to implement various actions, which we believe are probable of occurring and, as such, alleviate substantial doubt about the Company’s ability to continue as a going concern. A summary of these actions are as follows:

•We are closely managing our recurring operating expenses and limiting our non-recurring operating expenses over the next twelve-month period.
•We have completed the construction of our manufacturing facility in Buena, New Jersey and are limiting cash outflows for other capital expenditures. Moreover, we have the ability to delay other capital projects until such time that our liquidity improves, or we receive funding from outside sources.
•On November 12, 2018, the Company entered into a financing commitment whereby Ares Capital Management ("Ares") has agreed to loan the Company up to $120.0 million ("Ares Credit Facility"). The Ares Credit Facility will be secured by all of the Company's assets and will be funded in three tranches: (1) an asset based revolving credit facility of $25.0 million due November 2022 ("2022 Revolver"), (2) a term loan of $80.0 million due February 2023 ("2023 Term Loan"), and (3) a delayed draw term loan of $15.0 million also due in February 2023 ("2023 Delayed Draw Term Loan"). In addition, the Ares Credit Facility will require the Company to comply with certain affirmative non-financial covenants relating to periodic reporting and maintaining compliance with standard rules and regulations customary in the markets where the Company competes, as well as negative financial covenants limiting levels of indebtedness and restricting certain payments, as well as minimum revenue covenants for each twelve-month period ending December 31, 2018, March 31, 2019 and June 30, 2019, minimum consolidated adjusted EBITDA covenants for the twelve-month period ending September 30, 2019, December 31, 2019, March 31, 2020, June 30, 2020 and September 30, 2020 and minimum net leverage ratio covenants for the twelve-month period ending December 31, 2020 and ending each fiscal quarter thereafter until maturity. The 2023 Term Loan and 2023 Delayed Draw Term Loan will be subordinate to the 2022 Revolver. The proceeds from both the 2022 Revolver and 2023 Term Loan are anticipated to be funded in the fourth quarter upon execution of the final agreements with Ares, whereas the 2023 Delayed Draw Term Loan will be made available when the Company initiates capital improvements to substantially increase manufacturing capacity in its Buena, New Jersey injectable manufacturing facility, which is currently scheduled to begin in fiscal year 2019. The Company intends to use the proceeds from 2023 Term Loan to extinguish its existing $25.0 million 2021 Term Loan, as well as extinguish its remaining outstanding $68.7 million of December 2019 Notes. The 2022 Revolver will bear interest at a rate of LIBOR plus 3.75%, whereas the 2023 Term Loan and

2023 Delayed Draw Term Loan will bear interest at a rate of LIBOR plus 8.75% with a 24-month paid-in-kind interest option available to the Company should it choose to defer cash interest payments in order to provide further liquidity to continue launching new products.

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Out of Period Adjustments

For the three and nine months ended September 30, 2018, the Company recorded the following adjustments (in thousands) related to prior periods. The net impact of the adjustments on all prior annual or interim periods financial statements were not significant. There were no adjustments related to prior periods recorded for the three and nine months ended September 30, 2017.

	Three months ended September 30, 2018	**Nine months ended September 30, 2018**
Wholesale fees (Revenue)	$ —	$ 1,218
Chargebacks (Revenue)	(455)	(455)
Medicaid (Revenue)	—	297
Pricing and shipment adjustment (Revenue)	—	(502)
Sales return reserve (Revenue)	—	(577)
Inventory adjustments (Cost of revenues)	—	95
Capitalization of property, plant and equipment (Cost of revenues)	—	263
Bad debt expense (Selling, general and administrative expenses)	—	(578)
	$ (455)	$ (239)

3. Summary of Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the 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 historical valuation of the derivative liability, 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 for environmental cleanup and remediation costs. Actual results could differ from those estimates.

Cash Equivalents

The Company considers all highly liquid instruments purchased with the 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 is included within other assets on the Condensed Consolidated Balance Sheet. The Company also presents restricted cash with cash and cash equivalents in the Condensed Consolidated Statement of Cash Flows.

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

	September 30, 2018	**December 31, 2017**	**September 30, 2017**	**December 31, 2016**
Cash and cash equivalents	$ 15,267	$ 26,692	$ 38,231	$ 66,006
Restricted cash in other assets	472	473	475	475
Cash, cash equivalents and restricted cash in the statement of	$ 15,739	$ 27,165	$ 38,706	$ 66,481

cash flows

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, restricted stock units ("RSU's") and warrants issued as stock-based compensation. These pricing models utilize the market price of the Company’s common stock and the exercise price of the option or warrant, as well as time value and volatility factors underlying the positions. Stock-based compensation expense is recognized over the requisite service period of the award, which usually coincides with the vesting period of the grant.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, trade receivables, notes payable, accounts payable and other accrued liabilities at September 30, 2018 approximate their fair value for all periods presented. As of September 30, 2018, the net carrying value of the 2019 Notes and 2023 Notes (collectively the "Notes" and discussed in Note 7) was approximately $117.8 million compared to their face value of $143.75 million. This variance is due to the conversion feature in the Notes rather than to changes in market interest rates. The Notes carry a fixed interest rate and therefore are not subject to interest rate risk. As of September 30, 2018, the carrying value of the 2021 Term Loan (discussed in Note 7) was approximately $24.2 million compared to the face value of $25.0 million. The variance is due to debt discount and debt financing costs. The 2021 Term Loan bears interest at a rate of LIBOR plus 9%, and is therefore subject to market risk.

Loss Per 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 2019 and 2023 Notes, the exercise of options, and the vesting of RSU's. For the three and nine months ended September 30, 2018, the potential dilutive common stock equivalents have been excluded from the computation of diluted loss per share, as their effect would have been anti-dilutive.

(in thousands except shares and per share data)

	Three months ended September 30,		**Nine months ended September 30,**	
	2018	**2017**	**2018**	**2017**
Basic loss per share computation:				
Net loss - basic and diluted	$ (3,945)	$ (8,982)	$ (21,866)	$ (9,070)
Weighted average common shares - basic and diluted	53,625,768	53,391,948	53,532,277	53,297,889
Basic and diluted loss per share	$ (0.07)	$ (0.17)	$ (0.41)	$ (0.17)

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. See more detailed information in Note 4.

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 as discussed in Note 4. 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 Condensed Consolidated Balance Sheet, Condensed Consolidated Statement of Operations, and Condensed 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.

Property, Plant and Equipment

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

	Useful Lives
Buildings and Improvements	10 - 40 years
Machinery and Equipment	5 - 15 years
Computer Hardware and Software	3 - 5 years
Furniture Fixtures	5 years

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

Concentration of Credit Risk

Major customers of the Company are defined as those constituting greater than 10% of our total revenue. For the three months ended September 30, 2018, three of the Company's customers accounted for 49% of the Company's revenue, consisting of 25%, 12% and 12%, respectively. For the three months ended September 30, 2017, three of the Company's customers accounted for 54% of the Company's revenue, consisting of 33%, 11% and 10%, respectively. For the nine months ended September 30, 2018, three of the Company's customers accounted for 54% of the Company's revenue, consisting of 32%, 12% and 10%, respectively. For the nine months ended September 30, 2017, three of the Company's customers accounted for 52% of the Company's revenue, consisting of 28%, 12% and 12%, respectively. Accounts receivable related to the Company's major customers comprised 56% of all accounts receivable as of September 30, 2018, and 74% of all accounts receivable as of September 30, 2017. The loss of one or more of these major customers could have a significant impact on our revenues and harm our business and results of operations**.**

For the three months ended September 30, 2018, domestic net revenues were $13.3 million and foreign net revenues were $5.0 million. For the nine months ended September 30, 2018, domestic net revenues were $34.9 million and foreign net revenues were $14.2 million. As of September 30, 2018, domestic assets were $131.9 million and foreign assets were $61.0 million. For the three months ended September 30, 2017, domestic net revenues were $8.7 million and foreign net revenues were $2.6 million. For the nine months ended September 30, 2017, domestic net revenues were $36.5 million and foreign net revenues were $8.9 million. As of September 30, 2017, domestic assets were $121.2 million and foreign assets were $69.5 million.

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 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 Foreign currency exchange gain (loss) line item under the Other income (expense), section of the Condensed Consolidated Statement of Operations.

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 Condensed Consolidated Statement of Operations.

Adoption of Other Recent Accounting Pronouncements

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): "Restricted Cash (a consensus of the FASB Emerging Issues Task Force)". The update addresses the diversity in the industry with respect to classification and presentation of changes in restricted cash on the statement of cash flows. These amendments require that a statement of cash flows explain the restricted cash change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The amendments in this update were effective for fiscal years beginning after December 15, 2017 for public business entities, including interim periods within those fiscal years. For the Company, the amendments were effective January 1, 2018. The Company's adoption of this ASU was a full retrospective adoption, effective January 1, 2018, did not have a significant impact on its condensed consolidated financial statements.

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

In January 2017, the FASB issued ASU 2017-03, Accounting Changes and Error Corrections (Topic 250) and Investments-Equity Method and Joint Ventures (Topic 323): “Amendments to SEC Paragraphs Pursuant to Staff Announcements at the September 22, 2016 and November 17, 2016 EITF Meetings”. The update shows amendments to two SEC Announcements made late in 2016 regarding four specific standards as follows: ASU 2014-09, Revenue from Contracts with Customers (Topic 606), ASU 2016-02, Leases (Topic 842), ASU 2016-13, Financial Instruments - Credit Losses (Topic 326), and ASU 2014-01, Investments - Equity Method and Joint Ventures (Topic 323). The amendments in this update require changes to the U.S. GAAP Financial Reporting Taxonomy and the changes will be incorporated into the proposed 2018 Taxonomy which are available for public comment and finalized as part of the annual release process. The Company's adoption of this ASU, effective January 1, 2018, did not have a significant impact on its condensed consolidated financial statements.

In February 2017, the FASB issued ASU 2017-05, Other Income—Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20): “Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets”. This update addresses guidance for partial sales of nonfinancial assets. It affects (i) an entity that enters into a contract to transfer to a customer a nonfinancial asset, group of nonfinancial assets, or ownership interest in a consolidated subsidiary that is not a business or nonprofit entity, (ii) an entity that historically had transactions within the scope of the real estate-specific derecognition guidance, and (iii) an entity that contributes nonfinancial assets that are not a business or a nonprofit activity to a joint venture or other noncontrolled investee. The amendments were effective at the same time as the amendments in ASU 2014-09. Therefore, for the Company, the amendments were effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Public entities may apply the guidance earlier but only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company does not currently expect to enter into any such nonfinancial asset or ownership interest in its consolidated subsidiaries agreements but will refer to the guidance in ASU 2017-05 should that occur. The Company's adoption of this ASU, effective January 1, 2018, did not have a significant impact on its condensed consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation—Stock Compensation (Topic 718): “Scope of Modification Accounting”. This update provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718, Compensation—Stock Compensation, to a change to the terms or conditions of a share-based payment award. The amendments affect any entity that changes the

terms or conditions of a share-based payment award. The amendments are effective for fiscal years beginning after December 15, 2017. For the Company, the amendments were effective January 1, 2018. The Company has not made any changes to the terms or conditions of share-based payment awards but will refer to the guidance in ASU 2017-09 should that occur. The Company's adoption of this ASU, effective January 1, 2018, did not have a significant impact on its condensed consolidated financial statements.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842): “Recognition and Measurement of Financial Assets and Financial Liabilities”. The update supersedes Topic 840, Leases and requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. Topic 842 retains a distinction between finance leases and operating leases, with cash payments from operating leases classified within operating activities in the statement of cash flows. In July 2018, the FASB issued ASU 2018-11. The targeted improvements in the ASU provides: - an option to apply the transition provisions of the new standard at its adoption date instead of at the earliest comparative period presented in its financial statements, and - a practical expedient that permits lessors to not separate nonlease components from the associated lease component if certain conditions are met. The amendments in this update are effective for fiscal years beginning after December 15, 2018 for public business entities, which for the Company means January 1, 2019. The Company is reviewing all lease agreements inclusive of supplier agreements. The Company is currently evaluating the impact of this ASU on its condensed consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): “Simplifying the Test for Goodwill Impairment”. The update simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit’s goodwill with the carrying amount of that goodwill. For the Company, the amendments are effective January 1, 2020. The Company is currently evaluating the impact of this ASU on its condensed consolidated financial statements.

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

4. 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 Condensed Consolidated Statement of Operations.

Research and Development Services and Other Income

The Company establishes agreed upon product development agreements with its customers to perform product development services. 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, and 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.

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 makers. Net Sales (in thousands)

for the three and nine months ended September 30, 2018 and 2017 were as follows (prior-period amounts are not adjusted under the modified-retrospective method of adoption):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Company product sales	$ 16,375	$ 9,436	$ 44,288	$ 37,556
Contract manufacturing sales	1,878	1,883	4,626	7,707
Research and development services and other income	41	21	$ 174	$ 172
Revenue, net	$ 18,294	$ 11,340	$ 49,088	$ 45,435

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

	Three months ended September 30,		Nine months ended September 30,	
Company Product Sales	**2018**	**2017**	**2018**	**2017**
Topical	$ 10,503	$ 5,913	$ 26,297	$ 22,066
Injectables	5,872	3,523	17,991	15,490
Total	$ 16,375	$ 9,436	$ 44,288	$ 37,556

In the nine months ended September 30, 2018, 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 balances of $20.5 million and $31.8 million at September 30, 2018 and 2017, respectively. The allowance for doubtful accounts was $2.8 million and $2.2 million at

September 30, 2018 and 2017, respectively. These balances 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 also takes into account an estimate of the expected wholesaler sell-through levels to indirect customers at contract prices. The Company validates the chargeback accrual quarterly through a review of the inventory reports obtained from its largest wholesale customers. This customer inventory information is used to establish the estimated liability for future chargeback claims based on historical chargeback and contract rates. These large wholesalers represent a majority of the Company's chargeback payments. The Company continually monitors current pricing trends and wholesaler inventory levels to ensure the liability for future chargebacks is fairly stated.

Rebates are used for various discounts and rebates provided to customers. This account has been used for various one-time discounts given to customers. The Company reviews the percentage of products sold through these programs by reviewing chargeback data and uses the appropriate percentages to calculate the rebate accrual. Rebates are invoiced monthly 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.

The Company's adjustments for the deductions to gross product sales are as follows (in thousands):

	Three months ended September 30,		**Nine months ended September 30,**	
	2018	**2017**	**2018**	**2017**
Gross product sales	$ 40,111	$ 53,460	$ 124,801	$ 174,504
Deduction to gross product sales:				
Chargebacks and billbacks	10,739	30,954	49,103	105,059
Wholesaler fees for service	1,662	1,511	2,774	5,715
Sales discounts and other allowances	11,335	11,559	28,636	26,174
Total reduction to gross product sales	$ 23,736	$ 44,024	$ 80,513	$ 136,948
Company product sales, net	$ 16,375	$ 9,436	$ 44,288	$ 37,556

Financing and Payment

The Company's payment terms vary by the type and location of the customer and the products or services offered. The term between invoicing and when payment is due is not significant. Generally, the Company does not incur incremental costs to obtain contracts. The Company does not adjust revenue for the promised amount of consideration for the effects of a significant financing component because the Company's customers generally pay the Company within 100 days.

Costs to Obtain or Fulfill a Customer Contract

Sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in selling, general and administrative expense in the Condensed Consolidated Statements of Operations.

Costs related to shipping and handling are comprised of outbound freight and associated labor. The Company accounts for shipping and handling activities related to contracts with customers as fulfillment costs which are included in cost of sales in the Condensed Consolidated Statements of Operations.

In connection with five of the 32 products the Company currently manufactures, markets and distributes in its own label in the U.S., in accordance with an agreement entered into in December of 2011, the Company is required to pay a royalty calculated based on net sales to one of its pharmaceutical partners. The royalty is calculated based on contracted terms of 40% of net sales for the five products, which is to be paid quarterly to the pharmaceutical partner. Accounts payable and accrued expenses include $0.6 million and $0.6 million at September 30, 2018 and 2017, respectively, related to these royalties. Royalty expense of $0.5 million and $0.6 million was included in cost of sales in the Condensed Consolidated Statements of Operations for the three months ended September 30, 2018 and 2017, respectively. Royalty expense of $2.0 million and $1.4 million was included in cost of sales in the Condensed Consolidated Statements of Operations for the nine months ended September 30, 2018 and 2017, respectively.

5. Inventories

Inventories are valued at the lower of cost or net realizable value, using the first-in-first-out method and consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 11,093	$ 8,231
Work in progress	2,000	616
Finished goods	6,937	8,532
Inventories reserve	(2,148)	(1,304)
Inventories, net	$ 17,882	$ 16,075

6. Property, Plant and Equipment

Property, plant and equipment consists of the following (in thousands):

	September 30, 2018	December 31, 2017
Land	$ 401	$ 257
Building and improvements	17,486	8,613
Machinery and equipment	10,172	9,142
Computer hardware and software	4,111	3,244
Furniture and fixtures	519	449
Construction in progress	65,510	55,017
	98,199	76,722
Less accumulated depreciation and amortization	(9,812)	(8,367)
Property, plant and equipment, net	$ 88,387	$ 68,355

The Company recorded depreciation expense of $0.6 million and $0.4 million for the three months ended September 30, 2018 and September 30, 2017, respectively. The Company recorded depreciation expense of $1.7 million and $1.3 million for the nine months ended September 30, 2018 and September 30, 2017, respectively.

During the three months ended September 30, 2018 and September 30, 2017, there was $1.5 million of interest and $1.1 million of interest, respectively, capitalized as construction in progress. For the nine months ended September 30, 2018 and September 30, 2017, there was $4.4 million of interest and $2.3 million of interest, respectively, capitalized as construction in progress. This increase in capitalized interest is related to outstanding costs for the Company's facility expansion project in Buena. During the three months ended September 30, 2018 and September 30, 2017, there was $0.4 million of payroll costs and $0.2 million of payroll costs, respectively, capitalized into construction in progress. For the nine months ended September 30, 2018 and September 30, 2017, there was $1.5 million of payroll costs and $0.6 million of payroll costs, respectively, capitalized into construction in progress.

7. Debt

Convertible Notes

On December 16, 2014, the Company issued $125.0 million aggregate principal amount of Convertible 3.75% Senior Notes, due 2019 (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 2019 Notes. The 2019 Notes bear interest at a fixed rate of 3.75% per year, payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2015, and mature on December 15, 2019, unless earlier repurchased, redeemed or converted. The 2019 Notes are convertible into shares of the Company's common stock, cash or a combination thereof. On May 20, 2015, the Company received shareholder approval for the increase in the number of shares of common stock authorized and available for issuance upon conversion of the 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 new Convertible 4.75% Senior Notes due 2023 (the "2023 Notes"). The new 2023 Notes bear a fixed interest rate of 4.75% per year, payable semi-annually with the principal payable in May 2023. At the option of the holders, the 2023 Notes are convertible into shares of the Company's common stock, cash or a combination thereof. The initial conversion rate is $224.71 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 loan issue costs of $1.6 million upon issuance of the 2023 Notes.

In accordance with accounting for convertible debt within the cash conversion guidance of ASC 470-20, we allocated the principal amount of the 2023 Notes between its liability and equity components. The carrying amount of the liability component was determined by measuring the fair value of a similar debt instrument of similar credit quality and maturity that did not have the conversion feature. The carrying amount of the equity component, representing the embedded conversion option, was determined by deducting the fair value of the liability component from the principal amount of the 2023 Notes as a whole. The equity component was recorded to additional paid-in capital and is not remeasured as long as it continues to meet the conditions for equity classification. The excess of the principal amount of the 2023 Notes over the carrying amount of the liability component was recorded as a debt discount of $19.0 million, and is being amortized to interest expense using the effective interest method through the maturity date. We allocated the total amount of transaction costs incurred to the liability and equity components using the same proportions as the proceeds from the 2023 Notes. Transaction costs attributable to the liability component were recorded as a direct deduction from the liability component of the 2023 Notes, and are being amortized to interest expense using the effective interest method through the maturity date. Transaction costs attributable to the equity component were netted with the equity component of the 2023 Notes in additional paid-in capital. The effective interest rate of the 2023 Notes, inclusive of the debt discount and issuance costs, is 12.10%.

The exchange of $75.1 million of the 2019 Notes for the 2023 Notes is considered an 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 recorded $2.5 million of non-cash interest expense as an extinguishment loss related to the 2019 Notes in the Condensed Consolidated Statement of Operations. 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.

Term Loan

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On June 1, 2018, the Company entered into a credit agreement for $25.0 million secured by all Company assets, due June 1, 2021 (“2021 Term Loan”). The 2021 Term Loan has limited financial and non-financial covenants inclusive of a minimum cash carry balance of $5.0 million. The 2019 Notes and 2023 Notes are subordinate to the 2021 Term Loan. The first $15.0 million of loan proceeds was received on June 1, 2018. The remaining loan proceeds of $10.0 million were subject to closing conditions as defined in the agreement and were received on July 16, 2018. The 2021 Term Loan incurred loan issue costs of $0.5 million and a discount of $0.4 million. The discount is due to lender fees paid on the initial drawdown of $15.0 million. The issue costs and discount are recognized as interest expense over the term of the 2021 Term Loan. The 2021 Term Loan bears interest at a rate of LIBOR plus 9%, with a stated floor of 2%. The effective interest, inclusive of the debt discounts and issue costs is 12.78% as of September 30, 2018. As disclosed in Note 2, due to the lack of compliance with the non-financial covenant prescribed by our Term Loan, we reclassified the net carrying value of $24.2 million as current debt in the accompanying Condensed Consolidated Balance Sheet as of September 30, 2018.

At September 30, 2018 and December 31, 2017, the net carrying value of the debt and the remaining unamortized debt discounts and debt issuance costs were as follows (in thousands):

	September 30, 2018	**December 31, 2017**
Face amount of the 2019 Notes (non-current due December 2019)	$ 68,660	$ 143,750
Face amount of the 2021 Loan (current due June 2021)	25,000	—
Face amount of the 2023 Notes (non-current due May 2023)	75,090	—
	$ 168,750	$ 143,750
Less unamortized discounts and debt issuance costs	26,800	22,773
Total Carrying Value, Net	$ 141,950	$ 120,977

For the nine months ended September 30, 2018 and 2017, the Company recorded the following expenses in relation to the debt (in thousands):

Three Months Ended	**Nine Months Ended**

	September 30, 2018	2017	2018	September 30, 2017
Interest expense of the 2019 Notes (1)	$ 644	$ 1,348	$ 2,870	$ 4,043
Interest expense of the 2021 Loan	659	—	800	—
Interest expense of the 2023 Notes (1)	889	—	1,523	—
Debt partial extinguishment of 2019 Notes	—	—	2,467	—
Debt discount amortization of the 2019 Notes (1)	1,192	2,193	5,102	6,376
Debt discount amortization of the 2021 Loan	22	—	36	—
Debt discount amortization of the 2023 Notes (1)	717	—	1,215	—
Debt financing amortization of the 2019 Notes (1)	130	239	576	695
Debt financing amortization of the 2021 Loan	30	—	47	—
Debt financing amortization of the 2023 Notes (1)	62	—	104	—
Interest expense	$ 4,345	$ 3,780	$ 14,740	$ 11,114

(1) Included within "Interest and other expense, net" on the Condensed Consolidated Statements of Operations, offset by interest income and capitalized interest, as disclosed in Note 6.

8. Goodwill and Intangible Assets

Goodwill

The Company acquired the assets of Canadian pharmaceutical company Alveda Pharmaceuticals, Inc., in November 2015. As a result of the acquisition, we recorded goodwill of $0.4 million. We assess the recoverability of the carrying value of goodwill in the fourth quarter of each year, and whenever events occur or circumstances change that would,

more likely than not, reduce the fair value of our reporting unit below its carrying value. There have been no events or changes in

circumstances that would have reduced the fair value of our reporting unit below its carrying value from December 31, 2017, through September 30, 2018. No impairment losses were recognized during the nine months ended September 30, 2018.

Changes to the carrying value of goodwill during the nine months ended September 30, 2018 and the year ending December 31, 2017 were as follows (in thousands):

	Goodwill
Goodwill balance at December 31, 2016	$ 446
Foreign currency translation	25
Goodwill balance at December 31, 2017	$ 471
Foreign currency translation	(7)
Goodwill balance at September 30, 2018	$ 464

Intangible Assets

The following sets forth the major categories of the Company's intangible assets and the weighted-average remaining amortization period as of September 30, 2018 and December 31, 2017 (in thousands).

	September 30, 2018			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted Average Remaining Amortization Period (Years)
Trademarks and Technology	$ 39,167	$ (7,533)	$ 31,634	11.1
In process research and development	17,765	—	17,765	N/A

("IPR&D")				
Customer relationships	3,695	(1,049)	2,646	7.1
Total	$ 60,627	$ (8,582)	$ 52,045	

December 31, 2017

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted Average Remaining Amortization Period (Years)
Trademarks and Technology	$ 40,380	$ (5,684)	$ 34,696	12.8
In-process research and development ("IPR&D")	18,311	—	18,311	N/A
Customer relationships	3,783	(773)	3,010	7.9
Total	$ 62,474	$ (6,457)	$ 56,017	

Changes in intangibles during the nine months ended September 30, 2018 were as follows (in thousands):

	Trademarks and Technology	IPR&D	Customer Relationships
Balance at January 1, 2018	$ 34,696	$ 18,311	$ 3,010
Amortization	(2,022)	—	(280)
Loss on impairment	(7)	(15)	—
Foreign currency translation	(1,033)	(531)	(84)
Balance at September 30, 2018	$ 31,634	$ 17,765	$ 2,646

Assuming no additions, disposals or adjustments are made to the carrying values and/or useful lives of the intangible assets, annual amortization expense on product rights and other related intangibles as of September 30, 2018 over the remainder of 2018 and each of the next five years is estimated to be as follows (in thousands):

	Amortization Expense *	
2018 (remainder of the year)	$	765
2019	3,061	
2020	3,061	
2021	3,061	
2022	3,061	
2023	3,061	
Thereafter	18,210	
Total	$	34,280

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

The useful lives of the Company’s intangibles are as follows:

Intangibles Category	Amortizable Life
Trademarks and Technology	15
Customer Relationships	10

9. Stock-Based Compensation

Stock Options

The Company recognized $0.4 million and $0.5 million of compensation expense related to stock options during the three months ended September 30, 2018 and 2017, respectively, and $1.2 million and $1.7 million during the nine months ended September 30, 2018 and 2017, respectively.

The 1999 Director Stock Option Plan, as amended (the “Director Plan”), provides for the grant of stock options to non-employee directors of the Company at an exercise price equal to the fair market value per share on the date of the grant. As of December 31, 2017, an aggregate of 1,975,000 shares had been approved and authorized for issuance pursuant to the Director Plan with no change as of September 30, 2018. A total of 2,634,798 options had been granted to non-employee directors through December 31, 2017, with no change as of September 30, 2018. A total of 807,782 of those had been forfeited through December 31, 2017 and returned to the option pool for future issuance, with no change as of September 30, 2018. The options granted under the Director Plan vest in full one year after their respective grant dates and have a maximum term of ten years. As of December 31, 2017 and September 30, 2018 there were 500,000 shares of common stock options outstanding. As of December 31, 2017, the 147,984 options available were transferred to a plan that has superseded the Director Plan, as discussed further in this section, with no additional options transferred as of September 30, 2018.

The 1999 Stock Incentive Plan, as amended (“1999 Plan”), replaced all previously authorized employee stock option plans, and no additional options may be granted under those previous plans. Under the 1999 Plan, options or stock awards may be granted to all of the Company’s employees, officers, directors, consultants and advisors to purchase a maximum of 3,200,000 shares of common stock. However, pursuant to the terms of the 1999 Plan, no awards may be granted after March 16, 2009. A total of 2,892,500 options, having a maximum term of ten years, have been granted at 100% of the fair market value of the Company’s common stock at the date of grant. Options outstanding under the 1999 Plan were generally exercisable in cumulative increments over four years commencing one year from date of grant. As of September 30, 2018, there are no options outstanding under the 1999 Plan.

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. The 2009 Plan allows the Company to continue to grant options and restricted stock, as under the 1999 Plan, but also authorizes the Board of Directors to grant a broad range of other equity-based awards, including stock appreciation rights, restricted stock units (“RSUs”) and performance awards. The 2009 Plan has been created, pursuant to and consistent with the Company's current compensation philosophy, to assist the Company in attracting, retaining and rewarding designated employees, directors, consultants and other service providers of the Company and its subsidiaries and affiliates, in a manner that will be cost efficient to the Company from both an economic and financial accounting perspective. On April 12, 2010, the Board of Directors adopted, and the Company’s stockholders subsequently approved, an amendment and restatement of the 2009 Plan to increase the number of shares of Common Stock available for grant under such plan by adding 2,000,000 shares of Common Stock. The 2009 Plan, as amended on May 29, 2010, authorizes up to 5,000,000 shares of the Company’s common stock for issuance pursuant to the terms of the 2009 Plan. The maximum number of shares that may be subject to awards made to any individual in any single calendar year under the 2009 Plan is 1,000,000 shares. As of September 30, 2018, there were 22,710 RSUs outstanding, 1,493,960 shares of stock outstanding, and options to purchase 2,575,606 shares of common stock outstanding. As of December 31, 2017, there were 99,626 RSUs outstanding, 1,422,020 shares of stock outstanding and options to purchase 3,038,634 shares of common stock outstanding. As of December 31, 2017, the 249,052 options available were transferred to a plan that has superseded the 2009 Plan, as discussed further in this section. As of September 30, 2018, an additional 232,004 options available were transferred to the plan that superseded the 2009 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 shares of common stock that are represented by awards granted under our Director Plan and 2009 Plan that are forfeited, expire or are canceled without delivery of shares of common stock or which result in the forfeiture of shares of common stock back to the Company on or after May 25, 2016, 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 both the Director Plan and the 2009 Plan, any available shares from both are now incorporated into the 2016 Plan. As of September 30, 2018, there were 161,214 RSUs outstanding, 74,667 shares of common stock outstanding and options to purchase 1,319,738 shares of common stock outstanding under the 2016 Plan. As of December 31, 2017, there were 89,003 RSUs outstanding, 20,000 shares of common stock outstanding and options to purchase 761,176 shares of common stock outstanding under the 2016 Plan. As of September 30, 2018 and December 31, 2017, there were a total of 3,073,421 shares of common stock and 1,526,857 shares of common stock available under the 2016 Plan, respectively.

As of September 30, 2018 and December 31, 2017, there were options to purchase 4,395,344 and 4,299,810 shares of common stock outstanding, respectively, collectively in the Director Plan, 2009 Plan, and the 2016 Plan.

In the interest of maintaining consistency with the Company's 2016 Equity Incentive Plan, on March 13, 2017, the Company entered into (i) an amendment to the option agreements governing each option grant currently outstanding under the Company's 2009 Equity Incentive Plan, and (ii) an amendment to the RSU, agreements governing each RSU grant currently outstanding under the 2009 Plan. The amendments provide for the automatic vesting upon a change of control of the Company of each option grant and RSU grant, as applicable, outstanding under the 2009 Plan. The amendments had a de minimis value to the holders as of September 30, 2018, 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 using the Black-Scholes option-pricing formula that uses assumptions noted in the following table. Expected volatilities and risk-free interest rates are based upon the expected life of the grant.

	Nine Months Ended September 30,	
Assumptions	**2018**	**2017**
Expected dividends	—	—
Risk-free rate	2.78%	2.00%
Expected volatility	53.2% - 72.5%	58.0% - 69.7%
Expected term (in years)	3.2 - 3.3 years	3.2 - 3.3 years

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

A summary of option activity under the Director Plan, the 2009 Plan and the 2016 Plan as of September 30, 2018 and changes during the period are presented below:

	Number of	Weighted Average

	Options	Exercise Price	
Outstanding as of January 1, 2018	4,299,810	$	5.09
Issued	735,785	3.35	
Exercised	(236,000)	1.04	
Forfeited	(404,251)	7.71	
Expired	—	—	
Outstanding as of September 30, 2018	4,395,344	$	4.78
Exercisable as of September 30, 2018	3,247,214	$	4.74

The following tables summarize information regarding options outstanding and exercisable at September 30, 2018:

Outstanding:

Range of Exercise Prices	Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
$0.79 - $1.50	1,510,000	$ 1.06	3.38
$1.51 - $5.50	898,207	3.22	8.35
$5.51 - $10.67	1,987,137	8.31	7.21
Total	4,395,344	$ 4.78	6.12

Exercisable:

Range of Exercise Prices	Stock Options Exercisable	Weighted Average Exercise Price
$0.79 - $1.50	1,510,000	$ 1.06
$1.51 - $5.50	196,666	2.72
$5.51 - $10.67	1,540,548	8.60
Total	3,247,214	$ 4.74

As of September 30, 2018, the intrinsic value of the options outstanding was $5.0 million and the intrinsic value of the options exercisable was $4.6 million. As of September 30, 2018, there was $1.6 million of total unrecognized compensation expense related to non-vested share-based compensation arrangements granted under the Plan. The costs will be recognized through August 2021.

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 $0.1 million and $0.2 million of compensation expense during the three months ended September 30, 2018 and 2017, respectively, and $0.4 million and $0.7 million during the nine months ended September 30, 2018 and 2017, respectively, related to restricted stock and RSU awards. Stock compensation expense is recognized over the vesting period of the restricted stock and RSUs. At September 30, 2018, the Company had approximately $0.6 million of total unrecognized compensation cost related to non-vested restricted stock and RSUs, all of which will be recognized through April 2021. The following table summarizes the number of unvested RSUs and their weighted average exercise price for the nine months ended September 30, 2018.

	Number of RSUs	Weighted Average Exercise Price

Non-vested balance at January 1, 2018	188,629	$	8.27
Changes during the period:			
Shares granted	122,949	3.36	
Shares vested	(101,607)	9.07	
Shares forfeited	(26,047)	5.76	
Non-vested balance at September 30, 2018	183,924	$	4.90

10. Income Taxes

The Company's income tax expense (benefit) was $(0.1) million and $0.02 million for the three months ended September 30, 2018 and 2017, respectively. For the same two periods, the effective tax rates were 3.4% and 0.3%, respectively. The Company's income tax expense (benefit) was $(0.1) million and $0.1 million for the nine months ended September 30, 2018 and 2017, respectively and the effective tax rates were 0.4% and 1.5%, respectively. The income tax benefit during the three and nine months ended September 30, 2018 includes $0.1 million of foreign benefits recognized during the period.

The Company excludes from the calculation of the effective tax rate any entities that are projected to operate at a loss, have no tax benefit that can reasonably be expected, and those entities which operate in a zero tax rate jurisdiction. Due to continuing operating losses in the United States, the tax provision is based on minimum U.S. state income taxes and the operations of certain foreign affiliates that are subject to taxes in their respective countries

The Company has assessed the impacts of the changes resulting from the United States Tax Cuts and Jobs Act ("TCJA") and has recognized an income tax benefit and a corresponding receivable of $0.1 million related to the recoverability of Alternative Minimum Tax Credits during the 4th quarter of 2017. Deferred tax assets, liabilities and valuation allowances were remeasured at the new rate of 21% during the 4th quarter of 2017. There was no income impact resulting from the remeasurement since all U.S. net deferred tax assets are fully reserved by the Company.

In addition, the TCJA imposed a one-time transition tax on cumulative earnings, as defined, on foreign affiliates through December 31, 2017. This also had no impact on the earnings of the Company, since the included foreign affiliates operated at a cumulative deficit through December 31, 2017.

Beginning in 2018, the Company's net interest expense became subject to limitations imposed by the TCJA. Based on operating expectations, the Company will be subject to an interest expense limitation. Such limitation will serve to reduce the otherwise expected net operating loss and create an additional attribute related to the disallowed net interest expense and therefore is not expected to have an effect on earnings.

The passage of TCJA also included a new tax imposed on the current earnings of foreign subsidiaries called Global Intangible Low-Taxed Income ("GILTI"). Due to the complexity of the new GLITI tax rules, the Company continues to evaluate this provision of the TCJA and the application of ASC 740, *Income Taxes*. The Company is allowed to make an accounting policy choice of either (1) treating taxes due on future U.S. inclusions in taxable income related to GILTI as a current-period expense when incurred (the "period cost method") or (2) factoring such amounts into the Company's measurement of its deferred taxes (the "deferred method"). The Company's selection of an accounting policy with respect to the new GILTI tax rules will depend, in part, on analyzing its global income to determine whether it expects to have future U.S. inclusions in taxable income related to GILTI and, if so, what the impact is expected to be. Whether the Company expects to have future U.S. inclusions in taxable income related to GILTI depends on not only the Company's current structure and estimated future results of global operations, but also its intent and ability to modify its structure. The Company's currently in the process of analyzing its structure, however for 2018 the Company's foreign entities as a whole are expected to generate an operating loss. Therefore, the Company has not made any adjustments related to potential GILTI tax in its financial statements and has not made a policy decision regarding whether to record deferred tax on GILTI.

While the Company has completed its provisional analysis of the income tax effects of the TCJA, the related tax effects may need to be adjusted, possibly materially, due to further refinement of our calculations, changes in interpretations and assumptions that we have made, additional guidance that may be issued by regulatory bodies, and actions and related accounting policy decisions we may take as a result of the new legislation. We will complete our analysis over the one-year measurement period from the enactment of the law as provided for by "Income Tax Accounting Implications of the Tax Cuts and Jobs Act" (SAB 118), and any adjustments during this measurement

period will be included in net earnings from continuing operations as an adjustment to income tax expense in the reporting period(s) when such adjustments are determined.

The Company evaluates the recoverability of its net deferred tax assets based on its history of operating results, its expectations for the future and expiration dates. The Company has concluded that it is more likely than not it will be unable to realize the net deferred tax assets in the immediate future and has established a valuation allowance for all U.S. and foreign net deferred tax assets.

At December 31, 2017, the Company’s U.S. federal net operating loss carryforwards totaled $41.7 million. The Company’s ability to use net operating loss carry forwards is subject to limitation in future periods under certain provisions of Section 382 of the Internal Revenue Code of 1986, as amended, which limit the utilization of net operating

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

The Company is subject to the provisions of ASC 740-10-25, "*Income Taxes"* (ASC 740) which 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. For federal purposes, post 1998 tax years remain open to examination as a result of net operating loss carryforwards. The Company is currently open to audit by the appropriate state income taxing authorities for tax years 2013 to 2017. The Company has not recorded any liability for uncertain tax positions. Canadian taxing authorities have examined the returns of the Canadian affiliate for the years 2015 and 2016. The Company expects to receive the agency's report and has preliminarily been informed that there will be no adjustments.

11. Accrued Expenses

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

As of September 30, 2018 and December 31, 2017, the largest components of accrued expenses were (in thousands):

	September 30, 2018		**December 31, 2017**	
Interest expense	$	2,335	$	240
Payroll	1,595		1,580	
Professional fees	1,221		546	
Inventory and Supplies	1,191		58	
Capital expenditures	1,042		1,947	
Rebates	343		83	
Royalties	613		856	
Clinical studies	593		596	
Medicaid and Medicare	365		1,487	
Income Tax	30		58	
Other	1,109		650	

$	10,437	$	8,101

12. Legal and U.S. Regulatory Proceedings

The Company is involved from time to time in claims which arise in the ordinary course of business. In management's opinion, the Company has made adequate provision for potential liabilities, if any, arising from any such matters. However, litigation is inherently unpredictable, and the costs and other effects of pending or future litigation, governmental investigations, legal and administrative cases and proceedings (whether civil or criminal), settlements, judgments and investigations, claims and changes in any such matters, and developments or assertions by or against the Company relating to intellectual property rights and intellectual property licenses, could have a material adverse effect on its business, financial condition and operating results.

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

The class plaintiffs seek to represent nationwide or state classes consisting of persons who directly purchased, indirectly purchased, paid and/or reimbursed patients for the purchase of generic econazole from July 1, 2014 until the time the defendants' allegedly unlawful conduct ceased or will cease. On October 16, 2018 the court dismissed the class plaintiffs' claims against the Company with leave to replead.

The opt-out plaintiffs allege a conspiracy by thirty-five generic manufacturers to fix prices for thirty drug products, including econazole nitrate cream, in violation of federal antitrust laws. The opt-out plaintiffs seek treble damages for alleged price overcharges for the thirty drug products identified in the complaint during the alleged period of conspiracy, and also seek injunctive relief against the defendants. A motion to dismiss the opt-out plaintiffs' complaint has not yet been filed.

Due to the early stage of these cases, we are unable to form a judgment at this time as to whether an unfavorable outcome is either probable or remote or to provide an estimate of the amount or range of potential loss. We believe these cases are without merit, and we intend to vigorously defend against these claims.

On October 20, 2017, a Demand for Arbitration was filed with the American Arbitration Association by Stayma Consulting Services, Inc. ("Stayma") against the Company regarding the Company's development and manufacture for Stayma of two generic drug products, one a lotion and one a cream, containing 0.05% of the active pharmaceutical ingredient flurandrenolide. The Company developed the two products and Stayma purchased commercial quantities of each; however, Stayma alleges that the Company breached agreements between the parties by developing an additional and different generic drug product, an ointment, containing flurandrenolide, and failing to meet certain contractual requirements. Stayma seeks monetary damages. Because discovery in this matter is ongoing, the Company is unable to form a judgment at this time as to whether an unfavorable outcome is either probable or remote or to provide an estimate of the amount or range of potential loss. The Company believes this case is without merit, and the Company intends to vigorously defend against these claims. The Company filed a counter-claim against Stayma for its failure to pay several past due invoices of approximately $1.7 million relating to the development and commercial supply of the two subject products. These invoices have been fully reserved.

ITEM 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

This "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and other sections of this Quarterly Report on Form 10-Q contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, 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 based on current expectations of management and are not guarantees of future performance, and involve certain risks, uncertainties and assumptions, which are difficult to predict. These risks and uncertainties include, without limitation, competitive factors, outsourcing trends in the pharmaceutical industry, the general economic conditions in the markets in which the Company operates, levels of industry research and development spending, the Company’s ability to continue to attract and retain qualified personnel, the fixed price nature of product development agreements or the loss of customers and other factors described in the Company’s filings with the Securities and Exchange Commission, including the “Risk Factors” section as set forth in our Annual Report on Form 10-K for the year ended December 31, 2017, as updated below in this Quarterly Report on Form 10-Q. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in such forward-looking statements. The forward-looking statements set forth herein speak only as of the date of this report. 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 may be required by applicable law. The Company operates its business under one reportable segment.

As discussed in Note 1*, Correction of Previously Issued Unaudited Interim Condensed Consolidated Financial Statements*, in the Company’s unaudited interim condensed consolidated financial statements included in Item 1 of Part I “Financial Information”, the Company’s unaudited interim condensed consolidated financial statements for the quarter ended September 30, 2017 have been revised to give effect to the Revision. Accordingly, the discussion and analysis below for the three and nine-month periods ended September 30, 2017 have been revised to give effect to the Revision. The revised discussion and analysis presented below provides information to assist in understanding the Company’s financial condition and results of operations and, as such, should be read in conjunction with the Company’s unaudited interim condensed consolidated financial statements included in Item 1.

Company Overview

Strategic Overview

Teligent, Inc. and its subsidiaries (collectively the “Company”) 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. Our platform for growth is centered around the development, manufacturing and marketing a portfolio of generic pharmaceutical products in our own label in topical, injectable, complex and ophthalmic dosage forms. We believe that expanding our development and commercial base beyond topical generics, historically the cornerstone of our expertise, to include injectable generics, complex generics and ophthalmic generics (what we call our "TICO" strategy"), will leverage our existing expertise and capabilities, and broaden our platform for more diversified strategic growth.

Our pipeline includes 22 Abbreviated New Drug Applications ("ANDAs") for additional pharmaceutical products filed with the FDA. Our pipeline also includes one Prior Approval Supplement for our first opthalmic product filed in the second quarter 2017. We have three abbreviated new drug submissions ("ANDSs") on file with Health Canada. In addition, we have 39 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.

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 32 generic topical pharmaceutical products and four branded generic injectable pharmaceutical products. In Canada, we sell over 30 generic and branded generic injectable products and medical devices. Generic pharmaceutical products are bioequivalent to their brand name counterparts. We also provide contract manufacturing services to the pharmaceutical, ("OTC"), and cosmetic markets. We operate our business under one segment. Our common stock is traded on the NASDAQ Global Select Market under the trading symbol “TLGT.” Our principal executive office, laboratories and manufacturing facilities are located at 105 Lincoln Avenue, Buena, New Jersey. We have additional offices located in Iselin, New Jersey, Toronto, Canada, and Tallinn, Estonia.

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.

The three large wholesale drug distributors are AmerisourceBergen Corporation ("ABC"); Cardinal Health, Inc. ("Cardinal"); and McKesson Drug Company, ("McKesson"). 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 negative impact on our revenue, business, financial condition and results of operations. There are generally three major negotiating entities in the US market. Walgreens Boot Alliance, Inc. consists of Walgreens, AmerisourceBergen's PRxO Generics program, and Econdisc members. Red Oak Sourcing consists of CVS and Cardinal’s source program. Finally, ClarusOne consists of Walmart, RiteAid and McKesson’s OneStop program. A loss of any of these major entities could result in a significant reduction in revenue.

We consider our business relationships with ABC, Cardinal and McKesson to be in good standing and have fee for services contracts with each of them. However, a change in purchasing patterns, a decrease in inventory levels, an increase in returns of our products, delays in purchasing products and delays in payment for products by one or more of these distributors could have a material negative impact on our revenue, business, financial condition and results of operations. We continue to analyze the market for other 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.

For the three months ended September 30, 2018, we had sales to three customers, which individually accounted for 10% or more of our total revenue. Total sales to these customers represented 25%, 12%, and 12% , respectively, and represented 49% of total revenues. For the three months ended September 30, 2017, we had sales to three customers which individually accounted for more than 10% of our total revenue. Total sales to these customers represented 33%, 11% and 10%, respectively, and represented 54% of total revenues. For the nine months ended September 30, 2018, we had sales to three customers, which individually accounted for more than 10% of our total revenue. Total sales to these customers represented 32%, 12% and 10%, respectively, and represented 54% of total revenues. For the nine months ended September 30, 2017, we had sales to three customers, which individually accounted for more than 10% of our total revenue. Total sales to these customers represented 28%, 12% and 12%, respectively, and represented 52% of total revenues. Accounts receivable related to the Company’s major customers comprised 56% of all accounts receivable as of September 30, 2018, and 74% of all accounts receivable as of September 30, 2017.

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 three months ended September 30, 2018, approximately 80% of our contract manufacturing revenue was derived from pharmaceutical projects, as compared to 91% of total contract manufacturing revenue for the three months ended September 30, 2017. For the nine months ended September 30, 2018, approximately 78% of our contract manufacturing revenue was derived from pharmaceutical projects, as compared to 87% of total contract manufacturing revenue for the nine months ended September 30, 2017. None of our contract manufacturing services customers represented greater than 10% of total revenue for both the three months ended September 30, 2018 and September 30, 2017. None of our contract manufacturing services customers represented greater than 10% of total revenue for both the nine months ended September 30, 2018 and September 30, 2017.

Product and Pipeline Approvals

The following is a summary of significant approvals received in 2018:

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

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

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

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

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

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

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

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

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

On October 2, 2018, we announced approval of an ANDA for Fluocinonide Ointment USP, 0.05%. This was our tenth approval for 2018 and our twenty-ninth approval from our internally-developed pipeline of topical generic pharmaceutical medicines. We expect to launch this product in fourth quarter of 2019.

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

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

Out of Period Adjustments

For the three and nine months ended September 30, 2018, the Company recorded the following adjustments (in thousands) related to prior periods. The net impact of the adjustments on all prior annual or interim periods financial statements was not significant. There were no adjustments related to prior periods recorded for the three and nine months ended September 30, 2017.

	Three months ended September 30, 2018	Nine months ended September 30, 2018
Wholesale fees (Revenue)	$ —	$ 1,218
Chargebacks (Revenue)	(455)	(455)
Medicaid (Revenue)	—	297
Pricing and shipment adjustment (Revenue)	—	(502)
Sales return reserve (Revenue)	—	(577)
Inventory adjustments (Cost of revenues)	—	95
Capitalization of property, plant and equipment (Cost of revenues)	—	263
Bad debt expense (Selling, general and administrative expenses)	—	(578)
	$ (455)	$ (239)

Results of Operations

Three months ended September 30, 2018 compared to September 30, 2017

We had a net loss of $3.9 million, or $0.07 per share, for the three months ended September 30, 2018, compared to a net loss of $9.0 million, or $0.17 per share, for the three months ended September 30, 2017. Product Sales, net, include Company Product Sales and Contract Manufacturing Sales, as follows:

Revenues (in thousands):

	Three Months Ended September 30,		Increase/(Decrease)	
Components of Revenue:	2018	2017	$	%
Product sales, net	$ 18,253	$ 11,319	$ 6,934	61%
Research and development services and other income	41	21	20	95%
Total Revenues	$ 18,294	$ 11,340	$ 6,954	61%

Revenues were $18.3 million for the three months ended September 30, 2018, compared to $11.3 million for the same period in the prior year. This represents a $7.0 million increase in 2018 from the same period in the prior year. This increase in product sales of $7.0 million is attributed to the product launches of Diflorasone Diacetate Ointment and Clobetasol Propionate Cream.

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):

	Three Months Ended September 30,		Increase/(Decrease)	
	2018	2017	$	%
Cost of revenues	$ 11,575	$ 8,802	$ 2,773	32%
Selling, general and administrative expenses	4,845	5,971	(1,126)	(19%)
Product development and research expenses	3,087	4,606	(1,519)	(33%)
Totals costs and expenditures	$ 19,507	$ 19,379	$ 128	1%

Cost of revenues decreased as a percentage of total revenue to 63% for the three months ended September 30, 2018 as compared to 78% for the same period in 2017. The decrease in cost of sales as a percentage of revenue was driven by changes in product mix and pricing, in addition to customer and product mix for our contract services revenue. For the three months

ended September 30, 2018, cost of revenues also included an increase in inventory reserves of $0.6 million of costs related to the write-down of inventory and other costs. Some production inefficiencies can be attributed to the expanding of our manufacturing footprint and capacity in topical manufacturing, and adding sterile manufacturing capabilities at the existing facility.

Selling, general and administrative expenses for the three months ended September 30, 2018 decreased by $1.1 million as compared to the same period in 2017. For the three months ended September 30, 2018, there was a decrease in bad debt expense of $1.7 million primarily related to a specific customer account and $0.2 million in other costs, offset by an increase of $0.6 million in professional services and $0.2 million in salary and related costs.

Product development and research expenses for the three months ended September 30, 2018 decreased by approximately $1.5 million as compared to the same period in 2017. The decrease in product development and research expenses was primarily due to a decrease in clinical studies of $1.4 million and related testing of $0.1 million, a decrease in salary and related costs of $0.3 million offset by an increase in GDUFA fees of $0.2 million and an increase in business insurance of $0.1 million.

Other Expense (in thousands):

	Three Months Ended September 30,		(Increase)/Decrease	
	2018	2017	$	%
Debt partial extinguishment of 2019 Notes	$ —	$ —	$ —	—%
Interest and other expense, net	(2,693)	(2,663)	(30)	(1)%
Foreign currency exchange (loss) gain	(176)	1,744	(1,920)	(110)%
	$ (2,869)	$ (919)	$ (1,950)	212%

The increase for the three months ended September 30, 2018 is related to an increase in interest expense, amortization of debt discount and amortization of debt issuance costs related to the new debt offset by an increase in capitalized interest, from $1.1 million for the three months ended September 30, 2017 to $1.5 million for the three months ended September 30, 2018 (related to our facility expansion).

A foreign exchange loss of $0.2 million was recorded in the three months ended September 30, 2018, primarily related to the foreign currency translation of our intercompany loans denominated in U.S. dollars to our foreign subsidiaries. Depending on the changes in foreign currency exchange rates, we will continue to record a non-cash gain or loss on translation for the remainder of the term of these loans. Due to the nature of this transaction, there is no economic benefit to the Company to hedge.

Net Loss (in thousands, except per share numbers):

Three Months Ended	Increase/(Decrease)

	September 30, 2018	2017	$	%
Net loss attributable to common stockholders	$ (3,945)	$ (8,982)	$ 5,037	56%
Basic and diluted loss per share	$ (0.07)	$ (0.17)	$ 0.10	59%

Nine months ended September 30, 2018 compared to September 30, 2017

We had a net loss of $21.9 million, or $0.41 per share, for the nine months ended September 30, 2018, compared to a net loss of $9.1 million, or $0.17 per share, for the nine months ended September 30, 2017, which resulted from the following:

Revenues (in thousands):

	Nine Months Ended September 30,		Increase/(Decrease)	
Components of Revenue:	**2018**	**2017**	**$**	**%**
Product sales, net	$ 48,914	$ 45,263	$ 3,651	8%
Research and development services and other income	174	172	2	1%
Total Revenues	$ 49,088	$ 45,435	$ 3,653	8%

Revenues were $49.1 million for the nine months ended September 30, 2018, compared to $45.4 million for the same period in the prior year. This represents a $3.7 million increase in 2018 from the same period in the prior year. This increase in product sales of $3.7 million is attributed to the product launches of Hydrocortisone Butyrate Lotion, Diflorasone Diacetate Ointment and Clobetasol Propionate Cream.

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):

	Nine Months Ended September 30,		Increase/(Decrease)	
	2018	**2017**	**$**	**%**
Cost of revenues	$ 32,365	$ 23,926	$ 8,439	35%
Selling, general and administrative expenses	15,932	14,976	956	6%
Product development and research expenses	10,445	13,387	(2,942)	(22%)
Totals costs and expenditures	$ 58,742	$ 52,289	$ 6,453	12%

Cost of revenues increased as a percentage of total revenue to 66% for the nine months ended September 30, 2018 as compared to 53% for the same period in 2017. The increase in cost of sales as a percentage of revenue was driven by changes in product mix and pricing, in addition to customer and product mix for our contract services revenue. Production inefficiencies can be attributed to the expanding of our manufacturing footprint and capacity in topical manufacturing, and adding sterile manufacturing capabilities at the existing facility.

Selling, general and administrative expenses for the nine months ended September 30, 2018 increased by $1.0 million as compared to the same period in 2017. For the nine months ended September 30, 2018, there was an increase in professional fees of $1.7 million and salaries and related costs of $0.4 million, offset by a decrease in bad debt expense of $1.1 million ($1.7 million related to the Stayma case booked in 2017 - see Note 12, Legal and U.S. Regulatory Proceedings).

Product development and research expenses for the nine months ended September 30, 2018 decreased by approximately $2.9 million as compared to the same period in 2017. The decrease in product development and research expenses was primarily due to a decrease in clinical studies of $2.8 million and related testing of $0.7 million, a decrease in salary and related costs of $0.2 million, offset by an increase in GDUFA fees of $0.5 million and an increase of $0.3 million in overhead costs.

	Nine Months Ended September 30,		**(Increase)/Decrease**	
	2018	**2017**	**$**	**%**
Debt partial extinguishment of 2019 Notes	$ (2,467)	$ —	$ (2,467)	—%
Interest and other expense, net	(7,764)	(8,731)	967	11%
Foreign currency exchange (loss) gain	(2,071)	6,645	(8,716)	(131)%
	$ (12,302)	$ (2,086)	$ (10,216)	490%

As discussed in Note 7 in the Unaudited Condensed Consolidated Financial Statements included in Item 1 of Part 1 "Financial Information", on April 27, 2018, the Company entered into separate exchange agreements with certain holders of the 2019 Notes. There was a $75.1 million exchange of the 2019 Notes for 2023 Notes, which is considered a partial extinguishment, and which resulted in the acceleration of $2.5 million of non-cash interest expense for the nine months ended September 30, 2018. Interest expense decreased by $1.0 million for the nine months ended September 30, 2018 as compared to the same period in 2017. The decrease is related to the increase in capitalized interest, from $2.3 million for the nine months ended September 30, 2017 to $4.4 million for the nine months ended September 30, 2018 (related to our facility expansion), offset by an increase in interest expense, amortization of debt discount and amortization of debt issuance costs of the new debt. A foreign exchange loss of $2.1 million was recorded in the nine months ended September 30, 2018, as compared to a $6.6 million foreign exchange gain, recorded in the nine months ended September 30, 2017, primarily related to the foreign currency translation of our intercompany loans denominated in U.S. dollars to our foreign subsidiaries. Depending on the changes in foreign currency exchange rates, we will continue to record a non-cash gain or loss on translation for the remainder of the term of these loans. Due to the nature of this transaction, there is no economic benefit to the Company to hedge this transaction.

Net Loss (in thousands, except per share numbers):

	Nine Months Ended September 30,		**Increase/(Decrease)**	
	2018	**2017**	**$**	**%**
Net loss attributable to common stockholders	$ (21,866)	$ (9,070)	$ 12,796	141
Basic and diluted loss per share	$ (0.41)	$ (0.17)	$ 0.24	141

Liquidity and Capital Resources

Our cash flows from operating, investing and financing activities, as reflected in the Consolidated Statements of Cash Flows, are summarized in the following table (in thousands):

	Nine months ended September 30,	
	2018	**2017**
Net cash provided by (used in)		
Operating Activities	$ (15,314)	(2,660)
Investing Activities	$ (18,277)	(26,002)
	$ 22,707	269

Financing
Activities

Operating Activities

Our operating activities used $15.3 million of cash in the nine months ended September 30, 2018, compared to $2.7 million used during the same period last year. The cash used in operating activities for the nine months ended September 30, 2018 was a result of our net loss, adjusted for $18.7 million of non-cash expenses offset by a $12.2 million change in operating assets and liabilities. The change is related to a significant decrease in accounts payable and accrued expenses resulting from payments made towards our manufacturing expansion project. The cash used in operating activities for the nine months ended September 30, 2017 was a result of our net loss, adjusted for $9.5 million of non-cash expenses offset by a $3.2 million change in operating assets and liabilities.

Investing Activities

Our investing activities used $18.3 million during the nine months ended September 30, 2018, compared to $26.0 million of cash used in investing activities during the same period last year. The funds used for both periods were for capital expenditures, mainly related to the ongoing facility expansion located in Buena, New Jersey. The decrease during the nine months ended September 30, 2018 is due to the timing of payments directly related to our manufacturing expansion project.

Financing Activities

Our financing activities provided $22.7 million cash during the nine months ended September 30, 2018, compared to $0.3 million of cash provided during the nine months ended September 30, 2017. In the nine months ended September 30, 2018, $25.0 million was borrowed from the 2021 Term Loan, while $2.5 million was used to pay costs associated with the 2019 Notes, 2023 Notes and 2021 Term Loan. The $0.3 million of cash provided in the nine months ended September 30, 2017 consisted of proceeds from the exercise of options to purchase common stock.

Our principal sources of liquidity are cash and cash equivalents of approximately $15.3 million at September 30, 2018 and future cash from operations. Our working capital was $12.3 million at September 30, 2018.

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

On May 4, 2018, the Company filed Form S-3 under the Securities Act of 1933. The S-3 registration allows the Company 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.

On June 1, 2018, the Company entered into a credit agreement for $25.0 million, due June 1, 2021 ('2021 Term Loan") to support the operations of the business. The first $15.0 million of loan proceeds was received on June 1, 2018. The remaining loan proceeds of $10.0 million was received on July 16, 2018.

The Company did not file its financial statements for the quarter ended September 30, 2018 by the required SEC filing date. As a result, the Company's access to offer up to $50.0 million of the identified securities (filed on May 4, 2018) was suspended for twelve months. In addition, the late filing resulted in the Company being in default on its 2021 Term Loan which requires the Company to immediately pay all outstanding amounts based on the agreement. Due to the lack of compliance with the non-financial covenant prescribed by the Company’s 2021 Term Loan, the Company reclassed the net carrying value of $24.2 million as a current liability in the accompanying Condensed Consolidated Balance Sheet as of September 30, 2018. However, the Company intends to pay-off the existing $25.0 million of 2021 Term Loan with the funds received from the executed agreement with Ares Capital Management (See Subsequent Events Footnote 13). The lender is aware of the Company's intentions to pay the loan.

On November 12. 2018, the Company secured a credit agreement for $120.0 million. The facility includes three tranches of funding, an asset based revolving credit facility of $25.0 million due November 2022 (“2022 Revolver”), a term loan of $80.0 million due February 2023 (“2023 Term Loan”), and a delayed draw term loan of $15.0 million also due in February 2023 (“2023 Delayed Draw Term Loan”). Additional information is provided in Note 13 Subsequent Events. The Company intends to pay-off, within the next twelve months, the existing $25.0 million 2021 Term Loan executed earlier in the year as well as extinguish the remaining $68.7 million of December 2019 Notes.

The 2022 Revolver bears interest at a rate of LIBOR plus 3.75%, whereas the 2023 Term Loan and 2023 Delayed Draw Term Loan bear interest at a rate of LIBOR plus 8.75% with 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.

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.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles, which require management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from these estimates.

Please refer to our Annual Report on Form 10-K for the year ended December 31, 2017 for a complete list of all Critical Accounting Policies and Estimates. See also Item 1 for our Condensed Consolidated Financial Statements.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

As of September 30, 2018, our principal debt obligation was related to our 2019 and 2023 Notes. Interest accrues at a fixed rate of 3.75% on the outstanding principal amount of the 2019 Notes and is paid semi-annually every June 15 and December 15 until the 2019 Notes mature on December 15, 2019. Interest accrues at a fixed rate of 4.75% on the outstanding principal amount of the 2023 Notes and is paid semi-annually every May 1 and November 1 until the 2023 Notes mature on May 1, 2023. Since the interest rate is fixed, we have no market risk related to the 2019 and 2023 Notes.

On June 1, 2018, the Company entered into a credit agreement for $25.0 million secured by all Company assets, due June 1, 2021 (“2021 Term Loan”). The 2021 Term Loan bears interest at a rate of LIBOR plus 9%, and is therefore subject to market
risk.

On November 12. 2018, the Company secured a credit agreement for $120.0 million. The facility includes three tranches of funding, an asset based revolving credit facility of $25.0 million due November 2022 (“2022 Revolver”), a term loan of $80.0 million due February 2023 (“2023 Term Loan”), and a delayed draw term loan of $15.0 million also due in February 2023 (“2023 Delayed Draw Term Loan”). The 2022 Revolver bears interest at a rate of LIBOR plus 3.75%, whereas the 2023 Term Loan and 2023 Delayed Draw Term Loan bear interest at a rate of LIBOR plus 8.75% with 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. All three tranches of funding are subject to market risk.

Our financial instruments include cash and cash equivalents, accounts receivable, accounts payable and the Notes. The fair values of cash and cash equivalents, accounts receivable and accounts payable approximate book value because of the short maturity of these instruments. Based on the closing price of our common stock as of September 30, 2018, the fair value of our Notes was approximately $117.8 million compared to their face value of $143.75 million as of September 30, 2018. However, this variance is due to the conversion feature in the Notes rather than to changes in market interest rates. As noted above, the Notes carry a fixed interest rate and therefore do not subject us to interest rate risk.

At September 30, 2018, the majority of our cash and cash equivalents was invested in overnight instruments, the interest rates of which may change daily. Accordingly, these overnight investments are subject to market risk.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Based on the evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Securities Exchange Act of 1934) required by Rules 13a-15(b) or 15d-15(b) under the Securities Exchange Act of 1934, our Chief Executive Officer and our Chief Financial Officer have concluded that the Company has not maintained effective controls due to material weaknesses in internal control over financial reporting described in Part II, Item 9A of our 2017 Form 10-K for the year ended December 31, 2017 and a summary of such material weaknesses is as follows:

Control Environment

We did not maintain an effective control environment based on the criteria established in the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("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 condensed consolidated financial statements included in Item 1. "Financial Statements", these material weaknesses resulted in accounting errors.

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

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

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

Control Activities

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

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

· Lack of sufficient technical expertise within the accounting and financial reporting department as it relates to accounting for non-recurring complex debt transactions; and
· Ineffective controls over the application of accounting guidance in prior years related to the accounting for wholesaler fees, Medicaid and Medicare payments, and other rebates as well as improper disclosure related to the accounting for these fees upon adoption of FASB ASC 606, Revenue from Contracts with Customers, in the first quarter of fiscal year 2018;
· Ineffective controls over price concessions in Canada specifically, we have inadequate controls to ensure that the information necessary to properly record transactions is adequately communicated on a timely basis from non-financial personnel to those responsible for accounting and financial reporting;
· Ineffective controls over the application of accounting guidance and the Company's policy related to the allowance for doubtful accounts;
· Ineffective controls over the transition and implementation of the new accounting standard related to revenue recognition in the first quarter of 2018.

Information and Communication

We did not generate and provide quality information and communication based on the criteria established in the COSO framework. We have identified deficiencies in the principles associated with the information and communication component of the COSO framework. Specifically, these control deficiencies constitute material weaknesses, either individually or in the aggregate, relating to: (i) obtaining, generating, and using relevant quality information to support the function of internal control, (ii) communicating accurate information internally and externally, including providing information pursuant to objectives, responsibilities, and functions of internal control, and (iii) the monitoring of the design and operating effectiveness of controls related to the Company's key ERP third party service provider.

Notwithstanding the identified material weaknesses, management believes that the unaudited condensed consolidated financial statements included in this Form 10-Q fairly present in all material respects our financial condition, results of operations, and cash flows as of September 30, 2018.

Changes in Internal Control over Financial Reporting

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

Remediation Plan and Status

Our remediation efforts are ongoing and we will continue our initiatives to implement and document policies, procedures, and internal controls. Remediation of the identified material weaknesses and strengthening our internal control environment will require a substantial effort throughout 2019 and beyond, as necessary. We will test the ongoing operating effectiveness of the new and existing controls in future periods. The material weaknesses cannot be considered completely remediated until the applicable controls have operated for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

While we believe the steps taken to date and those planned for implementation will improve the effectiveness of our internal control over financial reporting, we have not completed all remediation efforts identified herein. Accordingly, as we continue to monitor the effectiveness of our internal control over financial reporting in the areas affected by the material weaknesses described above, we have and will continue to perform additional procedures prescribed by management, including the use of manual mitigating control procedures and employing any additional tools and resources deemed necessary, to ensure that our 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 certain steps to address material weaknesses in the control environment. Management team changes, including our Chief Financial Officer and Controller, are committed to implementing and maintaining an effective control environment that will drive a high level of integrity over internal control over financial reporting. Our Audit Committee and management have emphasized and continue to emphasize the importance of internal control over financial reporting, as well as the integrity of our financial statements.

Executive 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 that promotes compliance with GAAP and regulatory requirements.

We will hire new finance team members with the appropriate experience, certifications, education, and training for key financial reporting and accounting positions. To date, we hired a new senior leader in one of our foreign affiliates who, among other responsibilities, ensures customer contract terms and price concessions are reviewed with key members of the accounting and financial reporting department on a timely basis to appropriately reflect in the financial records. In addition, we hired new accounting and financial reporting team members and engaged external resources with significant experience with systems similar to the Company's ERP system and infrastructure to provide additional capacity, analytical and functional capabilities, and cross-training. The addition of skilled personnel will allow us to select and develop appropriate policies, procedures, and controls to strengthen our control environment.

Executive management will continue to evaluate the need for additional resources within our accounting and financial reporting, internal audit, and information technology functions. They will also continue to evaluate the effectiveness of these personnel and appropriateness of reporting lines across the company.

Control Activities

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

Information and Communication

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

PART II
OTHER INFORMATION

ITEM 1. Legal Proceedings

We are involved from time to time in claims which arise in the ordinary course of business. In the opinion of management, we have made adequate provision for potential liabilities, if any, arising from any such matters. However, litigation is inherently unpredictable, and the costs and other effects of pending or future litigation, governmental investigations, legal and administrative cases and proceedings (whether civil or criminal), settlements, judgments and investigations, claims and changes in any such matters, and developments or assertions by or against us relating to intellectual property rights and intellectual property licenses, could have a material adverse effect on our business, financial condition and operating results.

To date, twelve putative class action antitrust lawsuits have been filed against the Company along with co-defendants, including

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

The class plaintiffs seek to represent nationwide or state classes consisting of persons who directly purchased, indirectly purchased, paid and/or reimbursed patients for the purchase of generic econazole from July 1, 2014 until the time the defendants' allegedly unlawful conduct ceased or will cease. On October 16, 2018 the court dismissed the class plaintiffs' claims against the Company with leave to replead.

The opt-out plaintiffs allege a conspiracy by thirty-five generic manufacturers to fix prices for thirty drug products, including econazole nitrate cream, in violation of federal antitrust laws. The opt-out plaintiffs seek treble damages for alleged price overcharges for the thirty drug products identified in the complaint during the alleged period of conspiracy, and also seek injunctive relief against the defendants. A motion to dismiss the opt-out plaintiffs' complaint has not yet been filed.

Due to the early stage of these cases, we are unable to form a judgment at this time as to whether an unfavorable outcome is either probable or remote or to provide an estimate of the amount or range of potential loss. We believe these cases are without merit, and we intend to vigorously defend against these claims.

On October 20, 2017, a Demand for Arbitration was filed with the American Arbitration Association by Stayma Consulting Services, Inc. ("Stayma") against us regarding our 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. We developed the two products and Stayma purchased commercial quantities of each; however, Stayma now alleges that we breached agreements between the parties by developing an additional and different generic drug product, an ointment, containing flurandrenolide, and failing to meet certain contractual requirements. Stayma seeks monetary damages. Because discovery in this matter is ongoing, we are unable to form a judgment at this time as to whether an unfavorable outcome is either probable or remote or to provide an estimate of the amount or range of potential loss. We believe this case is without merit, and we intend to vigorously defend against these claims. We filed a counter-claim against Stayma for its failure to pay several past due invoices of approximately $1.7 million relating to the development and commercial supply of the two subject products. These invoices have been fully reserved.

ITEM 1A. Risk Factors

Part I, Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the year ended December 31, 2017 includes a detailed discussion of risks and uncertainties which could adversely affect our future results. Except as set forth below, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2017 have not materially changed.

Risks Related to Our Business

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

With the exception of 2015 and the three month period ended March 31, 2017, our expenses have exceeded our revenue in each of the last 12 years, and no net income has been available to common stockholders during each of

these years. As of September 30, 2018, our stockholders' equity was $35.7 million and we had an accumulated deficit of $82.0 million. Our future profitability depends on revenue exceeding expenses, but we cannot assure you that this will occur. If we do not become profitable or continue to raise external financing, we could be forced to curtail operations and sell or liquidate our business, and you could lose some or all of your investment.

We rely on a limited number of customers for a large portion of our revenues.

We depend on a limited number of customers for a large portion of our revenue. Three of our customers accounted for 49% of our revenue for the three months ended September 30, 2018, and three of our customers accounted for 54% of our revenue for the three months ended September 30, 2017. For the nine months ended September 30, 2018, three of our customers accounted for 54% of our revenue and for the nine months ended September 30, 2017, three of our customers accounted for 52% of our

revenue. The loss of one or more of these customers could have a significant adverse impact on our revenues and harm our business and results of operations.

Due to concentration of sales in 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, two of our products accounted for 17% of our revenue for the three months ended September 30, 2018. 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.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, and current and potential stockholders may lose confidence in our financial reporting.

We are required by the SEC to establish and maintain adequate internal control over financial reporting that provides reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We are likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses in those internal controls.

Since the determination regarding these material weaknesses, we have devoted, and will continue to devote, significant effort and resources to the remediation and improvement of our internal control over financial reporting. Our plans include the following: new internal and external personnel, new business process improvements and a review of relevant training. The elements of our remediation plan can only be accomplished over time and we can offer no assurance that these initiatives will ultimately have the intended effects. Any failure to maintain such internal controls or effectively implement our remediation plan could adversely impact our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations, which may have a material adverse effect on our business.

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

In the United States, we and our suppliers of raw materials are 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, financial condition 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 September 30, 2018, and remaining costs accrued at September 30, 2018 totaled $0.1 million. Based on information provided to us from our environmental consultants and what is known to date, we believe the reserves are sufficient for the remaining remediation of the environmental contamination. There is a possibility, however, that the remediation costs may exceed our estimates. In addition, we can give no assurance that the future cost of compliance with existing environmental laws will not give rise to additional significant expenditures or liabilities that would be material to us. Future events, such as new information, changes in existing environmental laws or their interpretation, and more vigorous enforcement policies of federal, state or local regulatory agencies, may have a material adverse effect on our business, financial condition and results of operations.

In Canada, we and our suppliers of raw materials are also subject to regulation under 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.

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

A significant amount of our total assets is related to goodwill and intangible assets. As of September 30, 2018, the value of our goodwill and intangible assets net of accumulated amortization was $52.5 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.

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

As of December 31, 2017, we had U.S. federal net operating losses (NOLs) of approximately $41.7 million which will expire from 2020 through 2037. The use of these NOLs may be limited in future years under IRC Section 382 which imposes an annual limitation on the amount of taxable income that can be offset by NOL carryovers and certain built in losses (collectively referred to as Pre-change Losses) that are attributable to the period preceding an ownership change. Under Code Section 382, an ownership change occurs when one or more “Five-percent Shareholders” increase their ownership in the corporation’s stock, in the aggregate, by more than fifty percentage points during a three-year testing period. An ownership change as defined by Code Section 382 occurred during 2010 and triggered a limitation under Code Section 382 on the usage of an aggregated $23.3 million of NOLs at the change date. We estimate that the annual limitation on such NOLs aggregates from $1.0 million to $2.3 million per year including the effect of amortization of built in gains. NOL's since the 2010 change date aggregate $23.1 million and we do not believe that these NOLs are subject to limitation. Limitation NOLs utilized aggregated $4.7 million as of December 31, 2017.

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

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

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

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

We have identified material weaknesses in our internal control over financial reporting, and if we are unable to satisfy regulatory requirements relating to internal controls, our stock price could suffer.

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

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

As required by Section 404 of the Sarbanes-Oxley Act of 2002, management has conducted an evaluation of the effectiveness of our internal control over financial reporting at September 30, 2018. We identified a number of material weaknesses in our internal control over financial reporting and concluded that, as of September 30, 2018, we did not maintain effective control over financial reporting based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. For a detailed description of these material weaknesses, see Item 4, "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. Moreover, other material weaknesses may be identified.

We are in the process of remedying all of the identified material weaknesses, and this work will continue during fiscal 2018 and beyond. For a detailed description of our remedial efforts, see Item 4, "Controls and Procedures." There can be no assurance as to when all of the material weaknesses will be remedied, if at all. Until our remedial efforts are completed, management will continue to devote significant time and attention to these efforts, and we will continue to incur expenses associated with the additional procedures and resources required to prepare our Consolidated Financial Statements. Certain of our remedial actions, such as hiring additional qualified personnel to implement our reconciliation and review procedures, will be ongoing and will result in our incurring additional costs even after our material weaknesses are remedied.

If we are unsuccessful in implementing or following our remediation plan, or fail to update our internal control over financial reporting as our business evolves or to integrate acquired businesses into our controls system, if additional material weaknesses are found in our internal controls in the future, or if our external auditors cannot attest to the effectiveness of our internal control over financial reporting, 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.

Risks Related to our Indebtedness

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 September 30, 2018, our total consolidated net indebtedness was $142.0 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. 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;
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•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.

Risks Related to Our Securities

Shares of our common stock are relatively illiquid which may affect the trading price of our common stock.

For the nine months ended September 30, 2018, the average daily trading volume of our common stock on the NASDAQ Global Select Market was approximately 573,874 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.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

None.

ITEM 5. Other Information

None.

ITEM 6. Exhibits

Exhibit Number	Description
31.1*	Certification of the President and Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification 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.
10.1*	The Company is filing a corrected copy of its Amended and Restated 2016 Equity

	Incentive Plan (the "2016 Plan") as Exhibit [10.1] hereto, in the interest of correcting a typographical error that appeared in the previous filing of the 2016 Plan. No other changes have been made to the 2016 Plan."
101*	The following financial information from this Quarterly Report on Form 10-Q for the period ended September 30, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statements of Operations; (ii) the Condensed Consolidated Balance Sheets; (iii) the Condensed Consolidated Statements of Cash Flows; (iv) the Condensed Consolidated Statement of Comprehensive Income(Loss); (v) the Condensed Consolidated Statement of Equity; and (vi) the Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

* Filed herewith.

SIGNATURES

Pursuant to the requirements 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.	
Date: December 12, 2018	By:	/s/ Jason Grenfell-Gardner
		Jason Grenfell-Gardner
		President and Chief Executive Officer
Date: December 12, 2018	By:	/s/ Damian Finio
		Damian Finio
		Chief Financial Officer

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32.2*	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
33.1*	Separation Agreement
10.1*	The Company is filing a corrected copy of its Amended and Restated 2016 Equity Incentive Plan (the "2016 Plan") as Exhibit [10.1] hereto, in the interest of correcting a typographical error that appeared in the previous filing of the 2016 Plan. No other changes have been made to the 2016 Plan."

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* Filed herewith.