

UNILIFE CORP

FORM 10-Q (Quarterly Report)

Filed 11/14/16 for the Period Ending 09/30/16

Address	250 CROSS FARM LANE YORK, PA 17406
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Sector	Healthcare
Fiscal Year	06/30

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from _____ to _____

Commission file number 001-34540

UNILIFE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

27-1049354
(I.R.S. Employer
Identification No.)

250 Cross Farm Lane, York, Pennsylvania 17406
(Address of principal executive offices)

Telephone: (717) 384-3400
(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 No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

As of November 9, 2016, 17,382,872 shares of the registrant's common stock were outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

UNILIFE CORPORATION AND SUBSIDIARIES
Consolidated Balance Sheets
(unaudited)

	September 30, 2016	June 30, 2016
	(in thousands, except share data)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 5,980	\$ 18,702
Restricted cash	2,092	2,400
Accounts receivable	2,050	374
Inventories	88	89
Prepaid expenses and other current assets	1,081	1,645
Total current assets	11,291	23,210
Property, plant and equipment, net	53,260	54,773
Goodwill	9,658	9,423
Other assets	257	255
Total assets	<u>\$ 74,466</u>	<u>\$ 87,661</u>
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	\$ 3,513	\$ 2,662
Accrued expenses	12,059	13,710
Current portion of long-term debt	673	669
Deferred revenue	3,798	1,660
Total current liabilities	20,043	18,701
Long-term debt, less current portion	108,560	104,445
Warrant liability	1,810	3,351
Derivative liability	353	347
Deferred revenue	46,532	47,550
Other long-term liabilities	661	—
Total liabilities	177,959	174,394
Contingencies (Note 11)		
Stockholders' Deficit:		
Redeemable convertible preferred stock, Series A — subject to redemption, \$0.01 par value, 790 shares authorized, 0 shares issued, and 0 shares outstanding as of September 30, 2016 and June 30, 2016	—	—
Preferred stock, \$0.01 par value, 50,000,000 shares authorized as of September 30, 2016; none issued and outstanding as of September 30, 2016 and June 30, 2016	—	—
Common stock, \$0.01 par value, 350,000,000 shares authorized as of September 30, 2016; 17,433,332 and 17,488,032 shares issued, and 17,348,575 and 17,411,651 shares outstanding as of September 30, 2016 and June 30, 2016, respectively	174	175
Additional paid-in-capital	399,874	398,862
Accumulated deficit	(503,336)	(485,363)
Accumulated other comprehensive income	614	380
Treasury stock, at cost, 84,757 shares as of September 30, 2016 and 76,381 shares at June 30, 2016	(819)	(787)
Total stockholders' deficit	(103,493)	(86,733)
Total liabilities and stockholders' deficit	<u>\$ 74,466</u>	<u>\$ 87,661</u>

See accompanying notes to the consolidated financial statements.

UNILIFE CORPORATION AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

	Three Months Ended September 30,	
	2016	2015
	(in thousands, except per share data)	
Revenue	\$ 1,713	\$ 3,187
Operating expenses:		
Research and development	6,803	16,004
Selling, general and administrative	8,178	9,228
Depreciation and amortization	1,690	1,543
Total operating expenses	16,671	26,775
Operating loss	(14,958)	(23,588)
Interest expense	4,286	1,684
Change in fair value of financial instruments	(1,261)	602
Other income, net	(10)	(10)
Net loss	(17,973)	(25,864)
Other comprehensive (income) loss, net:		
Foreign currency translation	(234)	816
Comprehensive loss	\$ (17,739)	\$ (26,680)
Net loss per share:		
Basic and diluted net loss per share	\$ (1.08)	\$ (2.08)

See accompanying notes to the consolidated financial statements.

UNILIFE CORPORATION AND SUBSIDIARIES
Consolidated Statement of Stockholders' Deficit
For the Three Months Ended September 30, 2016
(unaudited)

	<u>Common Stock</u>		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total
	Shares	Amount					
	(In thousands, except share data)						
Balance as of July 1, 2016	17,488,032	\$ 175	\$ 398,862	\$ (485,363)	\$ 380	\$ (787)	\$ (86,733)
Net loss	—	—	—	(17,973)	—	—	(17,973)
Foreign currency translation	—	—	—	—	234	—	234
Share-based compensation expense	(46,324)	(1)	1,012	—	—	—	1,011
Shares forfeited in lieu of payroll taxes	(8,376)	—	—	—	—	(32)	(32)
Balance as of September 30, 2016	<u>17,433,332</u>	<u>\$ 174</u>	<u>\$ 399,874</u>	<u>\$ (503,336)</u>	<u>\$ 614</u>	<u>\$ (819)</u>	<u>\$ (103,493)</u>

See accompanying notes to the consolidated financial statements.

UNILIFE CORPORATION AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(unaudited)

	Three Months Ended September 30,	
	2016	2015
	(in thousands)	
Cash flows from operating activities:		
Net loss	\$ (17,973)	\$ (25,864)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,690	1,543
Share-based compensation expense	1,011	3,584
Recognition of deferred revenue	(979)	(1,083)
Non-cash interest expense	4,068	557
Change in fair value of financial instruments	(1,261)	602
Non-cash sublease charge	709	—
Changes in assets and liabilities:		
Restricted cash - related party	—	2,264
Accounts receivable	(1,676)	168
Inventories	1	44
Prepaid expenses and other current assets	563	(550)
Other assets	(2)	6
Accounts payable	880	4,891
Due to related party	—	(2,264)
Accrued expenses	(1,568)	2,479
Deferred revenue	2,009	—
Other long-term liabilities	25	—
Net cash used in operating activities	(12,503)	(13,623)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(363)	(2,785)
Net cash used in investing activities	(363)	(2,785)
Cash flows from financing activities:		
Principal payments on long-term debt and capital lease obligations	(129)	(144)
Payment of royalty liability	(6)	(212)
Proceeds from former CEO loan	—	600
Proceeds from the issuance of common stock, net of issuance costs	—	9,342
Shares forfeited in lieu of payroll taxes	(32)	—
Decrease in restricted cash	308	308
Net cash provided by financing activities	141	9,894
Effect of exchange rate changes on cash	3	12
Net decrease in cash and cash equivalents	(12,722)	(6,502)
Cash and cash equivalents at beginning of period	18,702	12,303
Cash and cash equivalents at end of period	<u>\$ 5,980</u>	<u>\$ 5,801</u>
Supplemental disclosure of cash flow information		
Cash paid for interest	<u>\$ 218</u>	<u>\$ 1,782</u>
Supplemental disclosure of non-cash activities		
Purchases of property, plant and equipment in accounts payable and accrued expenses	<u>\$ 82</u>	<u>\$ 12,188</u>
Non-cash principal payments on long-term debt	<u>\$ 90</u>	<u>\$ —</u>

See accompanying notes to the consolidated financial statements.

1. Description of Business and Unaudited Financial Statements

Unilife Corporation (together with its subsidiaries, the “Company”) was incorporated under the laws of the State of Delaware in 2009 and is based in the Commonwealth of Pennsylvania. The Company began operations in Australia in 2002.

The Company is a designer, manufacturer, and supplier of innovative injectable drug delivery systems that can enhance and differentiate the injectable products of our pharmaceutical and biotechnology customers. While the Company has a broad portfolio of proprietary product platforms, the Company has focused the business on the Company’s wearable injector products. The Company believes its products are differentiated from conventional products, with innovative features and functionality designed to optimize the safe, simple, and convenient administration of injectable therapies. The majority of the Company’s products are designed for sale directly to pharmaceutical and biotechnology companies who are expected to supply them as drug-device combination products, pre-filled and ready for administration by end-users, such as patients or health-care providers. The Company customizes products within each of our platforms to address specific customer, therapy, patient and/or commercial requirements.

The Company is focusing primarily on active and new customer programs in its portfolio of wearable injector products, which the Company expects will improve our operating efficiencies and better position the Company to take advantage of commercial opportunities within the fast-growing market for wearable injectors. The Company’s wearable injector customers include Amgen Inc., MedImmune LLC (“MedImmune”), and Sanofi S.A. (“Sanofi”).

In addition to the filling, assembly and/or packaging of the Company’s products with injectable therapies, the Company’s customers are also, with respect to most of its products, responsible for the regulatory approval, sale and marketing of their final drug-device combination products. While at this point the Company’s products have not been sold to end users with the Company’s customers’ injectable therapies, the Company can generate revenue from customization programs, upfront fees, device and development materials, and exclusivity fees.

With the Company’s primary focus now on its wearable injector products, the Company performed an evaluation of its current contracts for its other products and determined that continued investment in those products is ultimately not beneficial to the Company at this time. The Company is currently in various stages of negotiation with the customers for such products to wind down its activities under those customer contracts. The Company does not expect that these negotiations will negatively impact its wearable injector programs and the outcome of these negotiations is still uncertain. Regardless of the result of such negotiations, the Company intends to continue to prosecute and maintain the intellectual property related to the majority of its non-wearable injector products in the event it becomes financially attractive for the Company to further develop and customize those products in the future.

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The accompanying unaudited consolidated financial statements contain all normal and recurring adjustments that, in the opinion of management, are necessary for a fair presentation for the periods presented as required by Rule 10-01 of Regulation S-X. Interim results may not be indicative of results for a full year. The accompanying unaudited consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and the notes thereto for the fiscal year ended June 30, 2016, or fiscal 2016, contained in its Annual Report on Form 10-K.

2. Internal Investigation and Listed Exchange Update

On May 8, 2016, the Company announced an investigation into violations of the Company’s policies and procedures and possible violations of laws and regulations by the Company’s former Chief Executive Officer, Alan Shortall, whose employment with the Company ceased on March 11, 2016, and its former Chairman, Jim Bosnjak, who resigned from the Company’s Board of Directors (the “Board”) on August 24, 2015 (the “Investigation”). The Board established a Special Committee to oversee the Investigation. Independent counsel conducted the Investigation with the assistance of an advisory firm with forensic accounting expertise. The Investigation was completed on October 7, 2016 and no material financial loss was identified.

The filing of the Company’s Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2016 (the “March 2016 10-Q”) and the Company’s Annual Report on Form 10-K for the fiscal year ended June 30, 2016 (the “2016 10-K”) were delayed as a result of the Investigation. In addition, the Company’s Annual Report on Form 10-K for the fiscal year ended June 30, 2015 and the Company’s Form 10-Q’s for the first and second quarters of the fiscal year 2016 were amended to correct immaterial misstatements to the financial statements and omissions of related party disclosures. As a result of such delay, on May 17, 2016 and September 19, 2016, the Company received notices from the Listing Qualifications department of The NASDAQ Stock Market LLC (“NASDAQ”) stating that, because the Company had not yet filed the March 2016 10-Q and the 2016 10-K, respectively, the Company was no

longer in compliance with NASDAQ Listing Rule 5250(c)(1), which requires listed companies to timely file all required periodic financial reports with the SEC. On September 8, 2016, NASDAQ granted the Company an exception until November 7, 2016 to regain compliance with NASDAQ Listing Rule 5250(c)(1). The Company filed the March 2016 10-Q and the 2016 10-K on October 24, 2016. On October 27, 2016, the Company received a notice from the Listing Qualifications department of NASDAQ stating that the Company is now in compliance with NASDAQ Listing Rule 5250(c)(1).

On October 17, 2016, the Company received a notice from the Listing Qualifications department of NASDAQ stating that, because the Company did not maintain a minimum Market Value of Listed Securities (“MVLS”) of \$50.0 million for the last 30 consecutive business days, the Company was no longer in compliance with NASDAQ Listing Rule 5450(b)(2)(A).

The Company has been provided a period of 180 calendar days, or until April 17, 2017, to regain compliance with the minimum MVLS listing requirement. If at any time on or before April 17, 2017, the MVLS of the Company’s common stock, par value \$0.01 per share (“common stock”), closes at \$50.0 million or more for a minimum of 10 consecutive business days, NASDAQ will provide the Company with written confirmation that the Company has achieved compliance with the minimum MVLS listing requirement and the matter will be closed.

In the event that the Company does not regain compliance with the minimum MVLS listing requirement on or before April 17, 2017, NASDAQ will provide the Company with written notification that its securities are subject to delisting. At that time, the Company would be permitted to appeal the delisting determination to a NASDAQ Hearings Panel or apply to transfer its common stock to The NASDAQ Capital Market (provided that it satisfied the requirement for continued listing on that market).

The Company was also required to file audited financial statements with the Australian Securities Exchange (the “ASX”) no later than September 30, 2016 (the “ASX Deadline”). The Company was not able to file such audited financial statements by the ASX Deadline. As a result, pursuant to ASX rules, trading in the Company’s CHES Depository Interests (“CDIs”) on the ASX was to be suspended prior to the opening of trading on the ASX on October 3, 2016, however, the ASX accepted the Company’s request for an immediate voluntary suspension of trading and as such, ASX halted trading of the Company’s CDIs on the ASX prior to the opening of trading on September 30, 2016 in Australia. As a result of the Company’s filing of audited financial statements with the ASX on October 24, 2016, trading of the Company’s CDIs on the ASX has resumed.

3. Liquidity

As of September 30, 2016, the Company’s cash and cash equivalents were \$6.0 million, restricted cash was \$2.1 million and the book value of the Company’s debt was \$109.2 million. Under the Company’s debt facilities, the Company is required to have a cash and restricted cash balance of \$5.1 million at September 30, 2016.

The Company incurred recurring losses from operations as well as negative cash flows from operating activities during fiscal year 2016 and the three months ended September 30, 2016, and anticipates incurring additional losses and negative cash flows until such time that it can generate sufficient revenue from the sale, customization, or exclusive use and licensing of its proprietary injectable drug delivery systems to pharmaceutical and biotechnology customers. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The Company has taken or intends to take the steps delineated below to address its cash requirements, the success of which is largely beyond the Company’s control.

The Company expects to generate cash receipts from wearable injector customers during fiscal year 2017 and the Company continues to have business development discussions with current and prospective wearable injector customers. The Company is, however, unable to predict the amount, if any, or the timing of such receipts or any proceeds from these business development discussions.

The Company has engaged a financial advisory firm to assist with fundraising efforts. There is no assurance that the financial advisory firm will be successful in these efforts.

In February 2016, the Company and Unilife Medical Solutions, Inc., a subsidiary of the Company (“Unilife Medical Solutions”) and, together with the Company, (the “Company Parties”) entered into a Securities Purchase Agreement (the “Counterparty SPA”) with Amgen Inc. (the “Counterparty”), pursuant to which the Counterparty agreed to purchase from the Company Parties a new series of 6% Senior Secured Convertible Notes Due 2023 in the aggregate original principal amount of up to \$55.0 million (the “Notes”). Pursuant to the Counterparty SPA, the Notes are issuable in up to three separate closings. The Company issued to Counterparty the first Note in the aggregate original principal amount of \$30.0 million on February 22, 2016, and Counterparty paid to the Company \$30.0 million in exchange therefor. Pursuant to the Counterparty SPA, the Counterparty may purchase up to an additional \$25.0 million in Notes, \$15.0 million (which amount has been reduced to \$5.0 million as a result of the issuance of the Accelerated

Convertible Note described below) of which may be purchased in January 2017 (the “2017 Convertible Note”) and \$10.0 million of which may be purchased in January 2018 (the “2018 Convertible Note”).

On October 24, 2016, the Company Parties and the Counterparty entered into a letter agreement (the “October Counterparty Letter Agreement”), pursuant to which the Company Parties agreed to issue to the Counterparty on October 24, 2016, in accordance with the terms and conditions of the Counterparty SPA and the October Counterparty Letter Agreement, a portion of the 2017 Convertible Note (the “Accelerated Convertible Note”) in the initial principal amount of \$10.0 million plus a \$0.6 million financing fee (the “Financing Fee”), for an aggregate initial principal amount of \$10.6 million. In consideration for issuing the Accelerated Convertible Note, the Counterparty paid to the Company \$10.0 million on October 24, 2016. Pursuant to the October Counterparty Letter Agreement, the Counterparty may purchase the remaining \$5.0 million of the 2017 Convertible Note in January 2017 in accordance with the terms and conditions of the Counterparty SPA. The Lender (as defined below) has the right to consent to the issuance of such \$5.0 million portion of the 2017 Convertible Note. There can be no assurance as to when or if the Counterparty will purchase all or any part of the remaining portion of the 2017 Convertible Note and/or the 2018 Convertible Note, or if the Lender (as defined below) will consent to the issuance of the remaining portion of the 2017 Convertible Note .

The Company’s ability to raise capital will be limited and there can be no assurance that financing will be available when needed. The Company will not be able to obtain financing through offerings of its securities registered under the Securities Act of 1933, as amended (“Securities Act”), for the near future and until the Company can prepare, file with the SEC, and cause to become effective a registration statement on Form S-1. We are not currently eligible to register the offer and sale of our securities using a registration statement on Form S-3, cannot use our existing Form S-3 and will not become eligible to use Form S-3 until we have timely filed certain periodic reports required under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) for 12 consecutive calendar months.

The Company believes its existing cash at September 30, 2016 and the proceeds from the Accelerated Convertible Note received on October 24, 2016 will provide the Company with sufficient liquidity to meet its minimum cash balance requirement of \$5.3 million and fund the Company’s operations through January 2017. The Company believes that the potential proceeds from business development discussions, the potential issuance of the remaining portion of the 2017 Convertible Note and fundraising efforts along with potential customer cash receipts, will provide the Company with enough liquidity to fund its operations for the next twelve months. However, there can be no assurance that any cash from such business development discussions, the potential issuance of the remaining \$5.0 million portion of the 2017 Convertible Note, fundraising efforts, or customer receipts will be available when needed, as such sources of liquidity largely are beyond the Company’s control. If we are unable to obtain financing when needed, we may be in default under one or more of our debt obligations unless we are able to obtain waivers from our lenders. A breach of any of the covenants related to our debt instruments could result in a higher rate of interest to be paid or the lenders could elect to declare all amounts outstanding under the applicable agreements to be immediately due and payable. If the lenders were to make such a demand for repayment, we would be unable to pay the obligations as we do not have existing facilities or sufficient cash on hand to satisfy these obligations. Under the circumstances, we also would be unable to pay our other obligations as they come due, which could prompt our creditors to pursue other remedies. These factors continue to raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

4. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Unilife Corporation and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires the Company’s management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The estimates are principally in the areas of revenue recognition, royalty liability valuation, derivative liability valuation, warrant liability valuation, preferred stock conversion liability (the “Preferred Stock Conversion”) valuation, share-based compensation expense, restructuring obligations, contingencies, recoverability of goodwill, long-lived assets and useful lives of property, plant and equipment. Management bases its estimates on historical experience and various assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

Property, Plant and Equipment

Property, plant and equipment, including significant improvements, are recorded at cost, net of accumulated depreciation and amortization. Repairs and maintenance are expensed as incurred.

Depreciation and amortization expense is recorded on a straight-line method over the estimated useful life of the asset as listed below:

Asset Category	Useful Lives
Building	40 years
Machinery and equipment	2 to 15 years
Computer software	3 to 7 years
Furniture and fixtures	3 to 7 years
Leasehold improvements	Shorter of leasehold improvement life or remaining term of lease

Interest cost incurred in connection with the development and construction of significant new machinery and equipment, as well as facility related costs have been capitalized as one of the elements of cost and are being amortized over the asset's respective useful life.

The Company evaluates the recoverability of the recorded value of long-lived assets periodically to determine if facts and circumstances exist that would indicate that the assets might be impaired or that the useful lives should be modified. As part of this valuation, the Company develops projections of undiscounted future cash flows of the asset or asset group. The projections of undiscounted cash flows include a combination of revenue from customization and development activities, capital expenses that may be necessary to support projected product sales and commercial product sales. As customization and development activities are completed, commercial product sales are expected to scale-up. Expectations of future commercial product sales included in the projections used for the impairment analysis are based on customer-specific information as well as market estimates relating to the anticipated drugs and therapies being targeted for use with the Company's products. These projections also include assumptions of future sales growth and profitability based on contracts entered into with customers as well as future contracts to be entered into based on the current discussions and negotiations with existing and prospective customers.

Sales projections are based on assumptions including a transition in the market toward patient self-administration of injectable therapies as well as transitions in the market toward biological-based drugs in the pharmaceutical industry development pipeline. The Company's future sales could also be impacted by factors such as its ability to obtain new and retain existing customers, the timing and extent of the customers' drug development activities as well as the regulatory approval process, drug efficacy and industry acceptance of injectable therapies. If the Company's future sales or its projections of future sales are impacted by any one or more of the preceding factors, it will reassess the recorded value of the long-lived assets. If impairment is indicated, an adjustment will be made to reduce the carrying amount of these assets to their fair value.

In connection with the Company's focus on wearable injector products, the Company evaluated the prospects of its non-wearable injector customer and supplier programs in fiscal year 2016. As a result of negotiations related to those supplier and customer programs and the Company's evaluation of those programs and potential disposition of certain assets, the Company determined that certain of its long lived-assets were impaired and the Company incurred a \$26.6 million non-cash asset impairment charge primarily related to machinery and equipment and construction in process in the third quarter of fiscal 2016.

There were no asset impairment charges for the three months ended September 30, 2016 and 2015.

Goodwill and Intangible Assets

Goodwill is the excess of purchase price over the fair value of net assets acquired in business acquisitions. Goodwill is subject to, at a minimum, an annual impairment assessment of its carrying value at the reporting unit level. Additional impairment assessments would be performed if events and circumstances warranted such additional assessments during the year. The Company has one reporting unit which includes its product lines, the base technology which it obtained as part of its November 2002 acquisition of Unित्रact Syringe Pty Limited, and the manufacturing capability which it obtained in its January 2007 acquisition of Integrated BioSciences, Inc.

As required under generally accepted accounting principles, the Company is required to evaluate goodwill for impairment at least annually and more frequently if certain trigger events occur. The Company determined that the continuing losses incurred by the Company and its negative equity, and the decline in the Company's stock price constituted trigger events that occurred in the quarter

ended September 30, 2016 requiring an evaluation of the carrying value of the Company's goodwill. Potential impairment of goodwill is identified by comparing the fair value with its carrying value.

The Company performed a goodwill valuation as of September 30, 2016 using a combination of the market approach and a discounted cash flow method under the income approach. The Company determined an overall business enterprise value (determined by the fair of equity plus the fair value of debt) by taking a weighted average from the results of the discounted cash flow under the income approach (40%) and the market approach based on the Company's market capitalization (60%). Under the income approach, the Company calculates the fair value of its reporting unit based on the present value of estimated future cash flows. Management judgment is necessary to evaluate the impact of operating and external market changes and to estimate the future cash flows used to measure fair value. The Company's estimate of cash flows considers past performance, current and anticipated market conditions, and internal projections and operating plans which incorporate estimates for sales growth, profitability and capital spending. Additional assumptions include forecasted growth rates and estimated discount rates which are risk adjusted for current market conditions. The Company believes such assumptions reflect current and anticipated market conditions and are consistent with those that would be used by other marketplace participants for similar purposes but are subject to change due to changing conditions. The weighting of the results of each method to assess the overall business enterprise value was considered reasonable as greater weight was given to the market capitalization based on the quoted stock price as this is considered more reliable information as it is publicly available and not subject to management judgment or estimate, whereas, discounted cash flow under the income approach is subject to management estimates and judgments.

Although based on the results of the business enterprise value calculation there was no indication of impairment of goodwill, the Company determined as a result of the continuing losses incurred by the Company and its negative equity, and other indicators of impairment and the decline in the Company's stock price, that an additional step 2 analysis was warranted under generally accepted accounting principles.

The Company performed a Step 2 valuation of goodwill by valuing certain intangible assets (primarily patents, trademarks and tradenames). The Company considered the impact of all assets and liabilities in allocating the fair value of the Company to determine the fair value of goodwill and whether any impairment is indicated. The Company believes these intangible assets would generate the most significant difference between implied fair value and book value as part of completing a Step 2 purchase price allocation for the purpose of determining the value of goodwill for impairment. The valuation of intangible assets was performed using the relief from royalty method under the income approach. This method utilizes the Company's revenue projections and assigns values based on determination of appropriate royalty rates considering relevant industry information. The Company then utilized the fair value of its intangible assets along with the estimated fair value of its other assets and liabilities to determine the implied goodwill compared to the carrying value of goodwill.

The residual fair value based on the results of the Step 2 valuation indicated there was no impairment of goodwill. The Company considered that the results of the valuation of goodwill indicated there was no impairment of goodwill and also indicated significant cushion between the implied fair value of goodwill and its carrying value and, therefore, the Company has concluded that no goodwill impairment existed as of September 30, 2016.

Definite-lived intangible assets include patents which are amortized on a straight-line method over their estimated useful lives of 15 years and are included in other assets. The Company reviews intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When factors indicate a possible impairment, if the sum of the estimated undiscounted future cash flows expected to result from the use and eventual disposition of an asset is less than the carrying amount of the asset, an impairment may be recognized. Measurement of an impairment loss is based on the excess of the carrying value of the asset over its fair value. Definite-lived intangible assets were less than \$0.1 million as of September 30, 2016 and June 30, 2016 and are recorded in other assets on the consolidated balance sheet. There were no impairments recorded on intangible assets during the three months ended September 30, 2016 and 2015.

Share-Based Compensation

The Company grants equity awards to its employees, directors, consultants and service providers. Certain employee and director awards vest over stated vesting periods and others also require achievement of specific performance or market conditions. The Company expenses the grant-date fair value of awards to employees and directors over their respective vesting periods. To the extent that employee and director awards vest only upon the achievement of a specific performance condition, expense is recognized over the period from the date management determines that the performance condition is probable of achievement through the date they are expected to be met. Awards granted to consultants and service providers are sometimes granted for past services, in which case their fair value is expensed on their grant date, while other awards require future service, or the achievement of performance or market conditions. Timing of expense recognition for consultant awards is similar to that of employee and director awards; however, aggregate expense is re-measured each quarter-end based on the then fair value of the award through the vesting date of the award.

The Company estimates the fair value of stock options using the Black-Scholes option-pricing model, with the exception of market-based grants, which are valued based on the Monte Carlo option pricing model. Option pricing methods require the input of highly subjective assumptions, including the expected stock price volatility.

Revenue Recognition

The Company recognizes revenue from industrialization and development fees, licensing fees and product sales. The Company recognizes revenue from sales of products at the time of shipment when title passes to the customer. The Company recognizes up front, non-refundable fees ratably over the expected life of the related agreement. The Company recognizes license revenue over the life of the patents of the products relating to the license. Revenue from industrialization and development fees is recognized as services are rendered, under the completed contract method, under the proportional performance method or upon achievement of the “at risk” substantive milestone events, which represent the culmination of the earnings process related to such events. Substantive milestones can include specific deliverables such as product design, prototype availability, user tests, manufacturing proof of principle and the various steps to complete the industrialization of the product. The terms of these contracts provide for customer payments to be made as services are rendered or substantive milestones are achieved. The Company considers whether a milestone is substantive at the inception of the agreement. The consideration earned from the achievement of a milestone must meet all of the following criteria to be considered substantive:

- It is commensurate with either of the Company’s performance to achieve the milestone, or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company’s performance to achieve the milestone;
- It relates solely to past performance; and
- It is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

Payment terms are considered to be standard commercial terms. Revenue is recognized when each substantive milestone has been achieved and the Company has no future performance obligations related to the substantive milestone. Fees for completed, substantive milestones, which are dependent upon customer acceptance for non-refundable payment or, if paid, are refundable pending customer acceptance are recognized upon customer acceptance or the termination of refund rights.

Fair Value Measurements

In accordance with Accounting Standards Codification (“ASC”) 820, Fair Value Measurements and Disclosures, the Company measures fair value based on a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. The fair value hierarchy is broken down into three levels based on the source of inputs.

The carrying value of financial instruments such as accounts receivable, accounts payable and accrued expenses are reasonable estimates of their fair value because of the short maturity of these items. The Company believes that the current carrying amount of its long-term debt approximates fair value because the interest rates on these instruments are similar to those rates that the Company would currently be able to receive for similar instruments of comparable maturity.

The Company has elected to measure its royalty agreement liability at fair value in accordance with ASC 825, Financial Instruments. The fair value of the royalty liability is based on significant inputs not observable in the market, which require it to be reported as a Level 3 liability within the fair value hierarchy. The valuation uses a methodology and assumptions that the Company believes would be made by a market participant. In particular, the valuation analysis uses a discounted cash flow methodology under the income approach based on the present value sum of payments to be made in the future. The fair value of the royalty agreement liability is estimated by applying a risk adjusted discount rate to the adjusted royalty revenue stream. These fair value estimates are most sensitive to changes in the payment stream.

The Company accounts for derivative financial instruments in accordance with ASC 815, Derivative and Hedging — Contracts in Entity’s Own Equity. Instruments which do not have fixed settlement provisions are deemed to be derivative instruments and are valued based on an average of a Monte Carlo and lattice model. The Preferred Stock Conversion valuation analysis used the estimated dividend rate based on the volume-weighted average price of the Company’s common stock at the date the Preferred Stock Conversion is measured. The warrant liability is valued using a Black-Scholes option-pricing model.

Interest Expense

The Company recognizes interest expense in the consolidated statements of operations and comprehensive loss for all debt instruments using the effective interest method. The effective interest method is a method of calculating the amortized cost of a financial liability and of allocating the interest expense over the relevant period. The effective interest rate is the rate that exactly discounts the estimated future cash payments through the expected life of the financial instrument to the net carrying amount of the financial liability. The application of the method has the effect of recognizing expense payable on the instrument evenly in proportion to the amount outstanding over the period to maturity or repayment. In calculating the effective interest rate, the Company estimates cash flows considering all contractual terms of the financial instrument, including fees for early redemption and all other premiums and discounts.

New Accounting Pronouncements Effective During the Period

In June 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-12 “Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved After the Requisite Service Period” which is part of ASC 718: Compensation-Stock Compensation. The guidance requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition and not be reflected in the estimate of the grant-date fair value of the award. The guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. The guidance became effective July 1, 2016 and the Company elected to apply the guidance prospectively for all awards granted or modified after the effective date. The adoption of the new guidance did not have a material impact on the Company’s financial condition, results of operations or cash flows.

New Accounting Pronouncements Not Yet Adopted

In August 2016, the FASB issued ASU No. 2016-15 “Statement of Cash Flows, Clarification of Certain Cash Receipts and Cash Payments”, which provides guidance on the presentation and classification of eight specific cash flow issues. Those issues are cash payment for debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instrument or other debt instrument with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; contingent consideration payments made after a business combination; cash received from settlement of corporate-owned life insurance policies; distribution received from equity method investees; beneficial interest in securitization transactions; and classification of cash receipts and payments that have aspect of more than one class of cash flows. The guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2017 with early adoption permitted. The Company is currently evaluating the impact this guidance will have on its consolidated financial statements.

In May 2014, FASB issued ASU 2014-09 “Revenue from Contracts with Customers” and amended by ASU 2016-08 “Principle versus Agent Considerations”, ASU 2016-10 “Identifying Performance Obligations and Licensing”, and ASU 2016-12 “Narrow-Scope Improvements and Practical Expedients”. The guidance requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to a customer. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In August 2015, the FASB issued ASU 2015-14 “Revenue from Contracts with Customers” which deferred the effective date of ASU 2014-09 for all entities by one year to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Early application is permitted only as of annual periods beginning after December 15, 2016, including interim reporting periods within that reporting period. With the deferral, the new standard is effective for the Company, on July 1, 2018, with early adoption permitted one year prior. The standard permits the use of either the retrospective or cumulative effect transition method. The Company has not selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In August 2014, FASB issued ASU 2014-15 “Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern”. The guidance requires an entity to perform a going concern assessment by evaluating its ability to meet its obligations for a look-forward period of one year from the financial statement issuance date. Disclosures are required if it is probable an entity will be unable to meet its obligations within the look-forward period. Incremental substantial doubt disclosure is required if the probability is not mitigated by management’s plans. The guidance is effective for all entities for the first annual period ending after December 15, 2016 and interim periods thereafter. Early application is permitted. The Company is currently evaluating the impact this guidance will have on its financial disclosures; however, as the guidance only impacts disclosure, the adoption of this guidance is not expected to have any impact on the Company’s financial condition, results of operations and cash flows.

In November 2015, the FASB issued new guidance simplifying the balance sheet classification of deferred taxes. The new guidance requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the new guidance. The new guidance is effective for the Company on July 1, 2017, with early adoption

permitted as of the beginning of an interim or annual reporting period. The new guidance may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company is evaluating the impact that the new guidance will have on its consolidated financial statements and related disclosures; however, at the present time the Company has recorded a valuation allowance against its deferred tax assets based on the history of losses incurred.

In January 2016, the FASB issued new guidance related to the recognition and measurement of financial assets and liabilities. The new guidance makes targeted improvements to GAAP impacting equity investments (other than those accounted for under the equity method or consolidated), financial liabilities accounted for under the fair value election, and presentation and disclosure requirements for financial instruments, among other changes. The new guidance is effective for the Company on July 1, 2018, with early adoption prohibited other than for certain provisions. The Company is evaluating the impact that the new guidance will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued guidance that will change the requirements for accounting for leases. The principal change under the new accounting guidance is that lessees under leases classified as operating leases will recognize a right-of-use asset and a corresponding lease liability. Current lease accounting does not require lessees to recognize assets and liabilities arising under operating leases on the balance sheet. Under the new guidance, lessees (including lessees under leases classified as finance leases and operating leases) will recognize a right-to-use asset and a lease liability on the balance sheet, initially measured as the present value of lease payments under the lease. Expense recognition and cash flow presentation guidance will be based upon whether the lease is classified as an operating lease or a finance lease (the classification criteria for distinguishing between finance leases and operating leases is substantially similar to the classification criteria for distinguishing between capital leases and operating leases under current guidance). The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The new standard must be adopted using a modified retrospective transition approach for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements; the guidance provides certain practical expedients. The Company is currently evaluating this guidance to determine its impact on the Company's results of operations, cash flows and financial position.

In March 2016, the FASB issued new guidance designed to simplify several aspects of the accounting for share-based payment transactions, including guidance relating to accounting for income taxes with respect to share-based payment awards; providing generally that excess tax benefits related to share-based awards should be recorded as a reduction to income tax expense (currently, excess tax benefits generally are recorded to additional-paid-in-capital); providing generally that excess tax benefits related to share-based awards should be classified along with other income tax cash flows as an operating activity (currently, excess tax benefits generally are separated from other income tax cash flows and classified as a financing activity); providing that an entity may make an accounting policy election either to base compensation cost accruals on the number of awards expected to vest (as required by current guidance) or to account for forfeitures when they occur; modifying the current exception to liability classification such that partial cash settlement of an award for tax withholding purposes would not result, by itself, in liability classification of the award if the amount withheld does not exceed the maximum statutory tax rate in the employees' applicable jurisdictions (currently, an award cannot qualify for equity classification, rather than liability classification, if the amount withheld exceeds the minimum statutory withholding requirements); and providing that cash paid by an employer when directly withholding shares for tax withholding purposes should be classified as a financing activity on the statement of cash flows (currently there is no authoritative guidance addressing this classification issue). The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted (if early adoption occurs in an interim period, any adjustments will be reflected as of the beginning of the fiscal year that includes the interim period). Depending on the particular issue addressed by the guidance, application of the guidance will be made prospectively, retrospectively or subject to a retrospective transition method. The Company is currently evaluating the potential impact of adopting this guidance on the Company's results of operations, cash flows and financial position.

5. Equity Transactions and Share-Based Compensation

The Company recognized share-based compensation expense related to equity awards to employees, directors, consultants and service providers of \$1.0 million and \$3.6 million during the three months ended September 30, 2016 and 2015, respectively.

On July 29, 2015, the Company entered into a Controlled Equity Offering Sales Agreement (the "New Sales Agreement") with Cantor Fitzgerald & Co., pursuant to which the Company may, from time to time, issue and sell shares of common stock, having an aggregate offering price of up to \$25.0 million. The Company issued 362,832 shares for net proceeds of \$4.6 million under the New Sales Agreement during the three months ended September 30, 2015. The Company used the proceeds for working capital needs and other general corporate purposes. The Company did not utilize this facility during the three months ended September 30, 2016.

On July 29, 2015, the Company entered into an equity purchase agreement (the "LPC Purchase Agreement") with Lincoln Park Capital Fund, LLC ("LPC"), pursuant to which the Company may sell, from time to time, to LPC up to \$45.0 million in shares of the

Company's common stock through July 2017, subject to certain limitations and conditions set forth in the LPC Purchase Agreement. The Company issued 324,465 shares of common stock to LPC and received net proceeds of \$4.8 million under the LPC Purchase Agreement during the three months ended September 30, 2015. The Company used the proceeds for working capital needs and other general corporate purposes. The Company did not utilize this facility during the three months ended September 30, 2016.

Stock Options and Warrants

The Company has granted stock options to certain employees and directors under the Employee Share Option Plan (the "Plan"). The Plan is designed to assist in the motivation and retention of employees and directors and to recognize the importance of employees and directors to the long-term performance and success of the Company. The Company has also granted stock options to certain service providers outside of the Plan. The majority of the options to purchase common stock vest on the anniversary of the date of grant, which ranges from one to three years. Share-based compensation expense related to options granted to employees and directors is recognized on a straight-line method over the related vesting term. Share-based compensation expense related to options granted to service providers is recognized ratably over each vesting tranche of the options.

In November 2009, the Company adopted the 2009 Stock Incentive Plan (the "Stock Incentive Plan"). The Stock Incentive Plan initially provided for a maximum of 600,000 shares of common stock to be reserved for the issuance of stock options and other stock-based awards. Commencing on January 1, 2012, and on each January 1st thereafter, through January 1, 2014, the share reserve automatically adjusted so that it was equal to 17.5% of the weighted average number of shares of common stock outstanding reduced by the sum of any shares of common stock issued under the Stock Incentive Plan and any shares of common stock subject to outstanding awards under the Stock Incentive Plan.

In November 2014, the Stock Incentive Plan was amended and restated (the "Amended and Restated 2009 Stock Incentive Plan" or "Amended Stock Plan") to change how the number of shares of common stock that may be issued under the Amended Stock Plan is calculated to increase the number of shares of common stock available for issuance under the Amended Stock Plan by 1.0 million and to reapprove the Amended Stock Plan for purposes of refreshing the stockholder approval requirement.

Under the terms of the LPC Purchase Agreement, the Company was required to obtain the consent of LPC prior to completing the Preferred Stock Purchase Agreement. The Company obtained such consent on November 9, 2015 and contemporaneously issued a five-year warrant to purchase 90,000 shares of common stock to LPC at an exercise price of \$10.00 per share. The Company performed a Black-Scholes valuation on the warrant and valued the warrant at \$5.40 per share of common stock. Accordingly, the Company recorded \$0.5 million during the three months ended December 31, 2015 associated with the issuance of the warrant as a component of redeemable convertible preferred stock issuance cost. LPC has not exercised any warrants as of September 30, 2016. On September 30, 2016, the Company performed a Black-Scholes valuation on the warrant liability to revalue the warrant and valued the warrant at \$0.58 per share of common stock. The warrant liability was revalued to \$0.1 million at September 30, 2016.

On February 22, 2016, in connection with entering into the Eighth Amendment to the Credit Agreement (as defined below) and the Sixth Amendment to the Royalty Agreement (as defined below), the Company issued to ROS (as defined below) warrants to purchase 1,673,981 shares of common stock, with an exercise price of \$12.50 per share, subject to adjustment for certain events, which may be exercised at any time and from time to time until February 22, 2026. ROS has not exercised any warrants as of September 30, 2016. Upon issuance, the Company performed a Black-Scholes valuation on the warrant and valued the warrant at \$7.20 per share of common stock. Accordingly, the Company recorded a \$12.1 million warrant liability during the three months ended March 31, 2016 associated with the issuance of the warrant. On September 30, 2016, the Company performed a Black-Scholes valuation on the warrant liability to revalue the warrant and valued the warrant at \$1.05 per share of common stock. The warrant liability was revalued to \$1.8 million at September 30, 2016.

The following is a summary of activity related to stock options held by employees and directors during the three months ended September 30, 2016:

	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Outstanding as of July 1, 2016	102,552	\$ 40.10		
Cancelled	(8,686)	49.25		
Outstanding as of September 30, 2016	<u>93,866</u>	<u>39.25</u>	<u>5.7</u>	<u>\$ 0</u>
Exercisable as of September 30, 2016	<u>78,366</u>	<u>\$ 39.79</u>	<u>5.6</u>	<u>\$ 0</u>

The following is a summary of activity related to stock options and warrants held by persons other than employees and directors during the three months ended September 30, 2016:

	Number of Options & Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of July 1, 2016	1,793,981	\$ 12.68		
Granted	—	0.00		
Expired	—	0.00		
Outstanding as of September 30, 2016	<u>1,793,981</u>	<u>\$ 12.68</u>	<u>9.0</u>	<u>\$ 0</u>
Exercisable as of September 30, 2016	<u>1,793,981</u>	<u>\$ 12.68</u>	<u>9.0</u>	<u>\$ 0</u>

The aggregate intrinsic value is defined as the difference between the market value of the Company's common stock as of the end of the period and the exercise price of the in-the-money stock options. There were no options exercised during the three months ended September 30, 2016 and 2015, respectively.

There were no options granted during the three months ended September 30, 2016 and 2015, respectively.

Restricted Stock Awards and Units

The Company has granted shares of restricted stock to certain employees, directors and consultants under the Amended and Restated 2009 Stock Incentive Plan. During the period prior to vesting, the holder of the non-vested restricted stock will have the right to vote and the right to receive all dividends and other distributions declared. All non-vested shares of restricted stock are reflected as outstanding; however, they have been excluded from the calculation of basic earnings per share.

For employees, the fair value of restricted stock is measured on the date of grant using the price of the Company's common stock on that date. Share-based compensation expense for restricted stock issued to employees is recognized on a straight-line basis over the requisite service period, which is generally the longest vesting period. For restricted stock granted to consultants, the fair value of the awards will be re-valued on a quarterly basis and marked to market until vested. Share-based compensation expense for restricted stock issued to consultants is recognized ratably over each vesting tranche.

The following is a summary of activity related to awards of restricted stock and restricted stock units during the three months ended September 30, 2016:

	Number of Restricted Stock Awards and Units	Weighted Average Grant Date Fair Value
Unvested as of July 1, 2016	882,948	\$ 15.41
Granted	313	2.78
Vested	(73,587)	32.45
Cancelled	(55,013)	6.48
Unvested as of September 30, 2016	<u>754,661</u>	<u>\$ 14.39</u>

Preferred Stock Purchase Agreement

On November 9, 2015, the Company entered into and closed a Preferred Stock Purchase Agreement (the "Preferred Stock Purchase Agreement") with the Fund. Pursuant to the Preferred Stock Purchase Agreement, the Company issued and sold to the Fund 790 shares of the Company's newly designated Series A Redeemable Convertible Preferred Stock of the Company, par value \$0.01 per share (the "Series A Preferred Stock"), at a 5% original issue discount and at a purchase price of \$10,000 per share for total gross proceeds to the Company of \$7.5 million. Prior to the full conversion of the Series A Preferred stock (as more fully discussed below), the Series A Preferred Stock was convertible into shares of common stock at a fixed conversion price of \$10.00 per share (the "Conversion Price"). The shares of Series A Preferred Stock were offered and sold in a registered direct offering (the "Offering") pursuant to the Company's shelf registration statement (File No. 333-197122), which was declared effective by the SEC on October 3, 2014.

From the date of issuance, each share of Series A Preferred Stock accrued dividends at a rate of 8.0% per annum (the “Dividend Rate”), subject to adjustment as discussed below, on its face value of \$10,000 (the “Face Value”), payable upon conversion or redemption of such share and when, as and if otherwise declared by the Board. Dividends were paid either in cash or in shares of common stock at the Company’s sole discretion and were valued at (i) if there was no Trigger Event (as defined below), (A) 95.0% of the average of the 5 lowest individual daily volume weighted average prices of the common stock on the Trading Market during the applicable Measurement Period, which may be non-consecutive, less \$0.50 per share of common stock, not to exceed (B) 100% of the lowest sales price on the last day of such Measurement Period less \$0.50 per share of common stock or (ii) following any Trigger Event, (A) 80.0% of the lowest daily volume weighted average price during any Measurement Period for any conversion by Holder, less \$1.00 per share of common stock, not to exceed (B) 80.0% of the lowest sales price on the last day of any Measurement Period, less \$1.00 per share of common stock. “Trigger Event” is defined as including, among other events, our breach of the Certificate of Designations and any transaction documents, the occurrence of certain defaults under our material agreements, the suspension of our NASDAQ listing, bankruptcy, the appointment of a receiver, our failure to timely file any report under the Exchange Act or the unenforceability of any material provision of the Certificate of Designations. “Trading Market” is defined as the principal trading exchange or market for the common stock. “Measurement Period” is defined as the period beginning on the date of issuance of any such shares of Series A Preferred Stock and ending, if no Trigger Event has occurred 3 trading days, and if a Trigger Event has occurred 30 trading days, after the number of shares have been delivered with respect to a conversion notice.

The Dividend Rate was adjusted (i) downward by an amount equal to 100 basis points for each amount, if any, equal to \$0.50 per share of common stock that the volume weighted average price of our common stock on any trading day rose above \$15.00, down to a minimum of 0.0%; and (ii) upward by an amount equal to 150 basis points for each amount, if any, equal to \$0.50 per share of common stock that volume weighted average price of our common stock on any trading day fell below \$7.00, up to a maximum of 15.0%. In addition, the Dividend Rate was adjusted upward by 10.0% upon any Trigger Event.

Each share of Series A Preferred Stock was convertible into such number of shares of common stock equal to the Face Value divided by the Conversion Price. Upon any conversion, the Company issued common stock at the Conversion Price and paid the dividend and conversion premium (“Dividend”) (in one instance in cash and the remaining instances in stock at the Company’s discretion). The Company was prohibited from issuing shares of common stock upon conversion of the Series A Preferred Stock if, as a result of the conversion, the holder, together with its affiliates, would beneficially own more than 4.99% of the total number of shares of the Company’s common stock then issued and outstanding, subject to adjustment up to 9.99% upon 61 days’ notice from the investor, which is referred to herein as the “Beneficial Ownership Limitation”. The Preferred Stock Purchase Agreement also contains representations, warranties and covenants customary for transactions of this type.

In November 2015 and December 2015, the Fund delivered to the Company notices of conversion totaling an aggregate of 300 shares of Series A Preferred Stock (the “Initial Conversion Notices”) and the Company issued an aggregate of 1,025,499 shares of common stock and paid \$0.3 million in cash to satisfy the Initial Conversion Notices. Calculations in the Initial Conversion Notices were based upon the occurrence of a Trigger Event.

As described above, the amount of any Dividend varied based on the Company’s share price during the applicable Measurement Period. If the Company’s share price declined during the Measurement Period with respect to a conversion notice, the number of shares owed to the Fund pursuant to such conversion notice would have changed and the Company was then required to issue the additional shares owed. During December 2015, the Company issued an additional 518,784 shares of common stock as additional Dividend with respect to the Conversion Notices as a result of a decline in the share price during the applicable Measurement Periods.

On January 4, 2016, the Fund delivered to the Company a notice of conversion for 40 shares of Series A Preferred Stock (the “January 4th Conversion Notice”) and together with the Initial Conversion Notices, the “Conversion Notices”) and the Company issued the Fund 246,036 shares of common stock. During January 2016, the Company issued an additional 162,706 shares of common stock as additional Dividend with respect to the Conversion Notices as a result of a decline in the share price during the applicable Measurement Periods.

On February 3, 2016, Company entered into the First Amendment to the Preferred Stock Purchase Agreement with the Fund. Pursuant to the First Amendment to the Preferred Stock Purchase Agreement, the Company acknowledged that the Fund had at all times fully and completely complied with all of its obligations under the Preferred Stock Purchase Agreement. The Fund has converted all of the Preferred Shares, and the parties entered into the First Amendment to the Preferred Stock Purchase Agreement to resolve the final and total of number shares of common stock to be delivered by the Company to the Fund as a result of the conversion.

Pursuant to the First Amendment to the Purchase Agreement, in full accord and satisfaction of all obligations under the Purchase Agreement and the remaining transaction documents (as defined in the Preferred Stock Purchase Agreement), the Company agreed to issue to the Fund an additional 831,668 shares (collectively, the “Shares”) of common stock, the approximate amount that may be issued under Nasdaq Listing Rule 5635(d) without shareholder approval which the Company did not obtain. On February 3, 2016, the

Company issued and delivered to the Fund 725,000 of the Shares. On February 11, 2016, the Company issued and delivered to the Fund the remaining 106,668 Shares.

Pursuant to the First Amendment to the Purchase Agreement, the Company has no further obligations to the Fund with respect to any of the Series A Preferred Stock, Conversion Notices (as defined in the Company's Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock) or any of the transaction documents. The Company issued 2,784,693 shares of common stock to the Fund in connection with the Preferred Stock Purchase Agreement, as amended by the First Amendment to the Preferred Stock Purchase Agreement. The Fund is no longer the holder of any Series A Preferred Stock.

The First Amendment to the Preferred Stock Purchase Agreement contained a mutual release of claims between the Company and the Fund and contained customary representations and warranties made by such parties. The Company also agreed to provide the Fund with indemnification for breaches of the First Amendment to the Preferred Stock Purchase Agreement and for certain third-party claims, and the Fund agreed to continue the same activity restrictions provided for in the Preferred Stock Purchase Agreement.

The Company accounted for the Series A Preferred Stock and the related Dividend as two separate units, i.e. Series A Preferred Stock and Preferred Stock Conversion. The Company determined that the Series A Preferred Stock should be classified as temporary equity based on the requirement to provide registered shares of the Company's common stock upon conversion and the related Dividend should be classified as a liability at fair value. Accordingly, the proceeds recorded as temporary equity for the Series A Preferred Stock represented the proceeds from the issuance less initial fair value of Preferred Stock Conversion and related issuance costs. As a result, on November 9, 2015, the Company recorded the net proceeds of \$7.2 million between the Series A Preferred Stock (\$2.8 million) and the initial Preferred Stock Conversion at its fair value (\$4.4 million). After accounting for all Conversion Notices and First Amendment to the Preferred Stock Purchase Agreement, the Redeemable Convertible Preferred Stock, Series A, was reclassified from temporary equity to permanent equity and was valued at \$0.0 million at March 31, 2016 and no further accounting was needed. The Preferred Stock Conversion was remeasured quarterly, and at March 31, 2016, the Preferred Stock Conversion was valued at \$0.0 and no further accounting was needed.

6. Property, Plant and Equipment

Property, plant and equipment consist of the following:

	September 30, 2016	June 30, 2016
	(in thousands)	
Building	\$ 32,362	\$ 32,362
Machinery and equipment	19,666	19,537
Computer software	2,986	2,986
Furniture and fixtures	792	1,386
Construction in progress	13,831	13,870
Land	2,036	2,036
Leasehold improvements	349	437
	<u>72,022</u>	<u>72,614</u>
Less: accumulated depreciation and amortization	(18,762)	(17,841)
Property, plant and equipment, net	<u>\$ 53,260</u>	<u>\$ 54,773</u>

Under *ASC 360 Property, Plant, and Equipment*, the Company is required to evaluate the recoverability of the carrying amount of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. In February 2016, the Company completed its review of strategic alternatives and announced the formation of a strategic collaboration centered upon the use of the Company's portfolio of prefilled, customizable wearable injectors. In connection with this focus, the Company has been evaluating the prospects of its non-wearable injector customer and supplier programs. As a result of negotiations related to those supplier and customer programs and the Company's evaluation of those programs and potential disposition of certain assets, the Company determined that certain of its long lived-assets were impaired during the third quarter of fiscal year 2016 and an impairment charge was recorded during that period. There were no impairment charges incurred for the three months ended September 30, 2016 and 2015.

Construction in progress as of September 30, 2016 consisted of amounts incurred in connection with machinery and equipment and facility related costs, including capitalized interest. Interest capitalized during the three months ended September 30, 2016 and 2015 was \$0.0 million and \$0.7 million, respectively.

7. Goodwill

The changes in the carrying amount of goodwill during the three months ended September 30, 2016 are as follows:

	(in thousands)	
Balance as of July 1, 2016	\$	9,423
Foreign currency translation		235
Balance as of September 30, 2016	\$	9,658

8. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2016	June 30, 2016
	(In thousands)	
Accrued payroll and other employee related expenses	\$ 3,049	\$ 2,755
Accrued cost related to equipment	1,720	2,623
Accrued transaction costs	5,000	5,000
Accrued professional fees	1,019	2,010
Accrued other	1,271	1,322
Total accrued expenses	\$ 12,059	\$ 13,710

Accrued transaction costs relate to the Company's review of strategic alternatives incurred in fiscal 2016.

9. Long-Term Debt

Long-term debt consists of the following:

	September 30, 2016	June 30, 2016
	(In thousands)	
10.25% Term loan, due March 2020	\$ 60,740	\$ 57,227
Royalty agreement liability	5,388	5,120
6.00% Senior secured convertible note, due February 2023	29,505	29,066
6.00% Mortgage loan, due December 2031	12,256	12,370
5.00% Commonwealth of Pennsylvania financing authority loan, due January 2021	1,963	1,977
	109,852	105,760
Less: unamortized debt discounts	(619)	(646)
	109,233	105,114
Less: current portion of long-term debt	(673)	(669)
Total long-term debt	\$ 108,560	\$ 104,445

Term Loan

On March 12, 2014, Unilife Medical Solutions, Inc., a wholly owned subsidiary of the Company (the "Borrower"), entered into a Credit Agreement with ROS Acquisition Offshore LP (the "Lender"), an affiliate of OrbiMed Advisors ("OrbiMed") (the "Credit Agreement," and, as amended the "Amended Credit Agreement" or the "OrbiMed Financing"). Pursuant to and subject to the terms of the Credit Agreement, the Lender agreed to provide term loans to the Borrower in the aggregate principal amount of up to \$60.0 million (the "Loans"). A first tranche loan of \$40.0 million was drawn on March 12, 2014 and a further two tranches each of \$10.0 million were committed by the Lender and were to be funded on each of December 15, 2014 and June 15, 2015, subject to and in accordance with the terms of the Credit Agreement. On September 30, 2014, the Borrower entered into a First Amendment to the Credit Agreement to accelerate the funding of the two additional tranches pursuant to which it received the proceeds from the first \$10.0 million tranche on October 1, 2014 and the proceeds from the second \$10.0 million tranche on November 10, 2014.

On October 13, 2015, the Company entered into the Third Amendment to the Credit Agreement, pursuant to which the Lender agreed to provide Borrower under the Amended Credit Agreement, up to an aggregate additional principal amount of \$10.0 million,

less fees and expenses incurred in connection with the Third Amendment to the Credit Agreement and the Second Amendment to the Royalty Agreement (as defined below). During the quarter ended December 31, 2015, the Company received the full amount of additional proceeds under the Amended Credit Agreement in the amount of \$10.0 million. The Third Amendment to the Credit Agreement also modified the Borrower's liquidity covenant whereby, under the Amended Credit Agreement, the Borrower is now required to maintain a cash balance of \$3.0 million as of October 13, 2015, rather than \$5.0 million.

The Loan bears interest at 9.25% per annum plus the greater of three-month LIBOR or 1.0%, payable in cash quarterly and as otherwise described in the Amended Credit Agreement. A default interest rate of 14.25% per annum plus the greater of three-month LIBOR or 1.0% shall apply during the existence of a default under the Amended Credit Agreement. The Loans are interest-only until March 12, 2020.

Unless the loan facility is otherwise terminated earlier pursuant to the terms of the Amended Credit Agreement, the Borrower is required to repay in full the unpaid principal amount of the Loans drawn down, together with all accrued and unpaid interest thereon plus a 10.0% repayment premium on March 12, 2020. The Borrower can make voluntary repayments at any time of any unpaid principal amount of the Loans, plus a 10.0% repayment premium. The Borrower must make mandatory prepayments in certain prescribed circumstances, including, without limitation, certain dispositions of assets and certain casualty events. In such events, the Borrower must prepay to Lender 100% of the net cash proceeds received.

The obligations of the Borrower under the Amended Credit Agreement are guaranteed by the Company and each of its subsidiaries and the Amended Credit Agreement is secured by the assets of the Company and its subsidiaries. The security interests granted by Borrower, the Company, Unilife Cross Farm LLC ("Cross Farm"), Unilife Medical Solutions Limited ("UMSL") and Unitract Syringe Pty Limited ("Unitract Syringe") are evidenced by, among other things, the Pledge and Security Agreement, dated as of March 14, 2014, by the Borrower, the Company, Cross Farm, UMSL, and Unitract Syringe in favor of Lender, for itself and as agent for Royalty Opportunities S.A.R.L. ("ROS"), the Mortgage and Security Agreement, dated March 12, 2014, by and between Cross Farm and Lender, for itself and as agent of ROS, and the General Security Deed, dated as of March 12, 2014, by Unitract Syringe, UMSL, and the Company in favor of the Lender, for itself and as agent of ROS.

The Amended Credit Agreement also contains certain customary covenants, as well as covenants relating to achieving minimum cash revenue targets at the end of each calendar year which has been eliminated as discussed below, maintaining a minimum liquidity target of \$3.0 million, and the execution of certain customer and employment agreements in form and substance satisfactory to lender. In the event of default, Borrower must prepay to Lender any unpaid principal amount of the loans drawn down, together with all accrued and unpaid interest thereon plus a 10.0% repayment premium. An event of default could also result in the Lender enforcing its security over the assets of Borrower, the Company, Cross Farm, UMSL and Unitract Syringe in accordance with the terms of the Amended Credit Agreement and the related security agreements. On June 30, 2015, the Company entered into a Second Amendment to the Credit Agreement to remove the minimum cash revenue target for the six month period ended June 30, 2015. On November 6, 2015, the Borrower received a waiver from the Lender of the minimum cash revenue target for the calendar year ending December 31, 2015. As of September 30, 2016, the Company is in compliance with all the loan covenants set forth in the Amended Credit Agreement.

In connection with entering into the Credit Agreement, the Borrower entered into a Royalty Agreement with ROS (the "Royalty Agreement") which entitles ROS to receive royalty payments.

On October 13, 2015, the Borrower entered into the Second Amendment to the Royalty Agreement (the "Amended Royalty Agreement") with ROS. Pursuant to and subject to the terms of the Second Amendment to the Royalty Agreement, Borrower has agreed to pay ROS 4.52% on the first \$50.0 million of net sales in each fiscal year, plus 1.75% of net sales in excess of \$50.0 million and up to and including \$100.0 million in each fiscal year, plus 0.438% of net sales in excess of \$100.0 million in each fiscal year, up from 3.875%, 1.50% and 0.375%, respectively. Borrower continues to have the right to buy out the Amended Royalty Agreement at any time on or before March 12, 2018 at a reduced amount; however, under the Amended Royalty Agreement, the buy-out amounts have increased. On March 13, 2017 and on March 13, 2018, the buy-out amount increases up to a maximum of approximately \$37.2 million under the Second Amendment to the Royalty Agreement, as compared to approximately \$26.3 million under the First Amendment to the Credit Agreement. The buy-out amount varies based on when the buy-out option is exercised and would, in each case, be reduced by amounts previously paid by Borrower to ROS pursuant to the Amended Royalty Agreement. In the event of default under the Amended Credit Agreement, OrbiMed will have a put option that will make the royalty amounts due immediately. The Amended Royalty Agreement has a term commencing on March 12, 2014 and ending on the earlier of (i) March 12, 2024 and (ii) the date of payment of the purchase price pursuant to the exercise of a put option by the Lender or the exercise of a buy-out option by the Borrower. As the Company has elected to value the Amended Royalty Agreement at fair value, the put option feature does not meet the criterion of ASC 815-15-25-1b and thus is not separated from the host contract and accounted for as a derivative instrument.

On December 31, 2015, the Borrower entered into a Fourth Amendment to the Credit Agreement with the Lender. Pursuant to and subject to the terms of the Fourth Amendment to the Credit Agreement, the Lender agreed to defer the due date for the December 31, 2015 interest payment (in the amount of \$1.7 million) (the "Interest Payment") to February 5, 2016. Additionally, the Borrower agreed to pay interest on such deferred amount from December 31, 2015 at the rate set forth in the Amended Credit Agreement and to pay all fees and expenses incurred by the Lender in connection with the Fourth Amendment to the Credit Agreement.

On January 31, 2016, the Borrower entered into the Fifth Amendment to the Credit Agreement with the Lender. Pursuant to and subject to the terms of the Fifth Amendment to the Credit Agreement, the Lender agreed to further defer the due date for the Interest Payment to February 9, 2016. Additionally, the Borrower agreed to pay interest on such deferred amount from December 31, 2015 at the rate set forth in the Amended Credit Agreement and to pay all fees and expenses incurred by the Lender in connection with the Fifth Amendment to the Credit Agreement.

On January 31, 2016, the Borrower entered into the Third Amendment to the Royalty Agreement with ROS. The Third Amendment to the Royalty Agreement became effective as of January 29, 2016. Pursuant to and subject to the terms of the Third Amendment to the Royalty Agreement, ROS agreed to defer the due date for (i) \$0.1 million of the January 30, 2016 royalty payment to February 1, 2016, and (ii) \$0.7 million of the January 30, 2016 royalty payment to February 9, 2016.

On February 9, 2016, the Borrower entered into the Sixth Amendment to the Credit Agreement with the Lender. Pursuant to and subject to the terms of the Sixth Amendment to the Credit Agreement, the Lender agreed to further defer the due date for the Interest Payment to February 16, 2016. Additionally, the Borrower agreed to pay interest on such deferred amount from December 31, 2015 at the rate set forth in the Amended Credit Agreement and to pay all fees and expenses incurred by the Lender in connection with the Sixth Amendment to the Credit Agreement.

On February 9, 2016, the Borrower entered into the Fourth Amendment to the Royalty Agreement with ROS. Pursuant to and subject to the terms of the Fourth Amendment to the Royalty Agreement, ROS agreed to defer the due date for \$0.7 million of the January 30, 2016 royalty payment to February 16, 2016.

On February 16, 2016, the Borrower entered into the Seventh Amendment to the Credit Agreement with the Lender. Pursuant to and subject to the terms of the Seventh Amendment to the Credit Agreement, the Lender agreed to further defer the due date for the Interest Payment to February 26, 2016. Additionally, the Borrower agreed to pay interest on such deferred amount from December 31, 2015 at the rate set forth in the Amended Credit Agreement and to pay all fees and expenses incurred by the Lender in connection with the Seventh Amendment to the Credit Agreement.

On February 16, 2016, the Borrower entered into the Fifth Amendment to the Royalty Agreement with ROS. Pursuant to and subject to the terms of the Fifth Amendment to the Royalty Agreement, ROS agreed to defer the due date for \$0.7 million of the January 30, 2016 royalty payment to February 26, 2016.

On February 22, 2016, the Borrower entered into the Eighth Amendment to the Credit Agreement with the Lender. Pursuant to and subject to the terms of the Eighth Amendment to the Credit Agreement, the Lender agreed to, among others, (i) defer all obligations of the Borrower to pay interest to the Lender for the period from January 1, 2016 through February 22, 2018 at the rate specified in the Amended Credit Agreement, which interest will be added to the outstanding principal amount of the loan on the last day of each interest period; (ii) enable the Counterparty to take a security interest in certain inventory and intellectual property assets related to a specific device licensed to the Counterparty (the "Collateral"); and (iii) remove the minimum cash receipts covenant for all future periods.

On February 22, 2016, the Borrower entered into the Sixth Amendment to the Royalty Agreement with ROS. Pursuant to and subject to the terms of the Sixth Amendment to the Royalty Agreement, ROS agreed to waive any rights to royalty payments otherwise payable as a result of the License Fee and the proceeds of the Notes, and to defer royalty payments payable on revenues received by the Company from the Counterparty until after the end of the first fiscal quarter in which the Company sells a commercial quantity of devices developed for the Counterparty.

In connection with entering into the Eighth Amendment to the Credit Agreement and the Sixth Amendment to the Royalty Agreement, the Company issued to ROS a warrant to purchase 1,673,981 shares of common stock, with an exercise price of \$12.50 per share, subject to adjustment for certain events, which may be exercised at any time and from time to time until February 22, 2026. In respect to the consideration provided to ROS in the form of the warrant and the terms of the Eighth Amendment to the Credit Agreement and the Sixth Amendment to the Royalty Agreement, the Company evaluated whether the debt was modified or extinguished pursuant to ASC 470-50, Debt – Modifications and Extinguishments. The Company determined that the previous debt was extinguished and recorded the modified debt at fair value (\$51.3 million). The Company recorded a gain on debt extinguishment for the quarter ended March 31, 2016 of \$2.9 million which consisted of the remeasurement of the debt at fair value offset by

the value of the warrant as of the Counterparty Effective Date and the deferred financing costs previously associated with the term loan.

On September 30, 2016, the Borrower entered into a letter agreement (the “OrbiMed Letter Agreement”) with the Lender pursuant to which the Lender agreed to waive (a) the requirements in Sections 7.1(c) and 7.1(d) of the Amended Credit Agreement for the Borrower to provide audited financial statements of the Company together with certain other information within 90 days after the end of the Company’s fiscal year ended June 30, 2016, provided that the Borrower furnishes such information by the earlier of (i) November 7, 2016, and (ii) five business days of when the Company files the 2016 10-K with the SEC, and (b) any “Event of Default” that has occurred or would occur under Section 9.1(c) of the Amended Credit Agreement, solely as a result of thereof.

Pursuant to the OrbiMed Letter Agreement, the Lender also agreed to waive any “Event of Default”, if any, through September 30, 2016 under Section 9.1(c) of the Amended Credit Agreement as a result of any failure to furnish the Lender notice of any new Material Agreement (as defined in the Amended Credit Agreement) or amendments or terminations of Material Agreements within the timeframe set forth in Section 7.1(m) of the Amended Credit Agreement, but only to the extent that that Borrower provided any such notices to the Lender prior to September 30, 2016.

The Borrower made certain representations and warranties to the Lender in the OrbiMed Letter Agreement with respect to the content of the September Counterparty Letter Agreement (as defined below). In reliance on such representations and warranties, the Lender waived any Event of Default under Section 9.1(f) of the Amended Credit Agreement that may have occurred as a result of any breach of Section 6.3 of the Counterparty SPA, solely due to the Company’s delay in timely filing the Exchange Act Filings (as defined below) with the SEC. There were no other changes to the terms of the Amended Credit Agreement in connection with the OrbiMed Letter Agreement.

The Borrower and ROS entered into a letter agreement dated October 20, 2016 (the “ROS Letter Agreement”), pursuant to which ROS agreed, until 11:59 p.m. New York City time on July 1, 2017, to waive all rights under the Amended Credit Agreement and the other Loan Documents (as defined in the Amended Credit Agreement) to declare an “Event of Default” or other breach under such documents as a result of the Company’s or the Borrower’s failure to maintain an effective registration statement, as required by the warrant issued by the Company to ROS, dated February 22, 2016, to purchase 1,673,981 shares of common stock. Pursuant to the ROS Letter Agreement, ROS acknowledged and agreed that the Borrower’s receipt of notice of the effectiveness of a registration statement would cure any such breach.

In accordance with the ROS Letter Agreement, ROS also agreed to waive all rights under the Amended Credit Agreement and the other Loan Documents to declare an “Event of Default” or other breach under such documents as a result of the Company’s or the Borrower’s failure to timely file documents (the “Delayed Filings”) with the U.S. Securities and Exchange Commission (the “SEC”) or ASX since February 22, 2016. Pursuant to the ROS Letter Agreement, ROS acknowledged and agreed that the filing by the Borrower of the Delayed Filings with the SEC and the ASX will cure any such breach so long as the Borrower files such Delayed Filings by November 7, 2016.

In connection with the entering into of the October Counterparty Letter Agreement, on October 24, 2016, the Company Parties and certain of the Company’s other subsidiaries entered into the Ninth Amendment (the “Ninth Amendment to the Credit Agreement”) to the Amended Credit Agreement with the Lender. Pursuant to the Ninth Amendment to the Credit Agreement, the Lender agreed to waive (i) compliance with Section 8.9 of the Amended Credit Agreement solely to permit the entering into of the October Counterparty Letter Agreement, and (ii) any event of default that would occur under Section 9.1(c) of the Amended Credit Agreement solely with respect to the October Counterparty Letter Agreement. In addition, the Ninth Amendment to the Credit Agreement amended the Amended Credit Agreement to provide for the issuance of the Accelerated Convertible Note and the execution of the October Counterparty Letter Agreement.

The Company determined that the Amended Credit Agreement and the Amended Royalty Agreement should be accounted for as two separate units. Accordingly, the Company allocated the proceeds from the Loans on a residual basis between the two units based on their relative fair values. As a result, on February 22, 2016, the royalty liability was determined to have a fair value of \$7.0 million and the initial \$40.0 million provided under the Credit Agreement was allocated to the remaining proceeds of \$33.0 million. The \$20.0 million from the two additional tranches that were funded during the three months ended March 31, 2015 and the \$10.0 million received during the three months ended December 31, 2015 were reflected as incremental debt. The carrying value of the debt will be accreted to the face value over the loan term based on the effective interest rate. The royalty liability will be adjusted to fair value on a quarterly basis. As of September 30, 2016, the fair value of the royalty liability was \$5.4 million.

There are cross-default provisions in the Amended Credit Agreement, Metro Bank loan (as described below) and Keystone/CFA Loan (as described below), so that a default under one agreement could trigger a default under the others. Metro Bank, the Lender

under the Amended Credit Agreement, Keystone Redevelopment Group, LLC and Commonwealth Financing Authority are parties to an intercreditor agreement.

Senior Secured Convertible Note

On February 22, 2016, the Company and certain of its subsidiaries entered into a Securities Purchase Agreement (the “Counterparty SPA”) with Amgen Inc. (the “Counterparty”), pursuant to which Counterparty agreed to purchase from the Company a new series of 6% Senior Secured Convertible Notes Due 2023 in the aggregate original principal amount of up to \$55.0 million (the “Notes”). The Notes may be issued in up to three separate closings. The Company issued to Counterparty the first Note in the aggregate original principal amount of \$30.0 million on February 22, 2016 (the “2016 Convertible Note”) and Counterparty paid to the Company \$30.0 million in exchange therefor. Per the Counterparty SPA, the Counterparty may purchase up to an additional \$25.0 million in Notes, \$15.0 million (which amount has been reduced to \$5.0 million as a result of the issuance of the Accelerated Convertible Note described below) of which may be purchased in January 2017 (the “2017 Convertible Note”) and \$10.0 million of which may be purchased in January 2018 (the “2018 Convertible Note”).

On October 24, 2016, the Company Parties and the Counterparty entered into the October Counterparty Letter Agreement, pursuant to which the Company Parties agreed to issue to the Counterparty on October 24, 2016, in accordance with the terms and conditions of the Counterparty SPA and the October Counterparty Letter Agreement, a portion of the 2017 Convertible Note (the “Accelerated Convertible Note”) in the initial principal amount of \$10.0 million plus the \$0.6 million financing fee (the “Financing Fee”), for an aggregate initial principal amount of \$10.6 million. In consideration for issuing the Accelerated Convertible Note, the Counterparty paid to the Company \$10.0 million on October 24, 2016.

Pursuant to the October Counterparty Letter Agreement, the remaining \$5.0 million portion of the 2017 Convertible Note will continue to be issuable in January 2017 by the Company Parties to the Counterparty in accordance with the terms and conditions of the Counterparty SPA. The Lender has the right to consent to the issuance of such \$5.0 million portion of the 2017 Convertible Note. There can be no assurance as to when or if the Counterparty will purchase all or any part of the remaining portion of the 2017 Convertible Note and/or the 2018 Convertible Note, or if the Lender will consent to the issuance of the remaining portion of the 2017 Convertible Note.

Interest under each of the 2016 Convertible Note and the Accelerated Convertible Note (together, the “Outstanding Counterparty Notes”) accrues at a rate of 6% per year and will be paid quarterly in arrears through the addition of the amount of such interest to the then outstanding principal amount. All or part of the principal and accrued interest on each of the Outstanding Counterparty Notes will be repaid through (i) discounted pricing on purchases by the Counterparty of the Company’s products, (ii) credits taken by the Counterparty against development and customization fees for devices, and (iii) credits against per-unit royalties otherwise payable to the Company for the manufacture and sale of the Company’s products. Any repayment will be applied to the Outstanding Counterparty Notes in the order of their issuance. In addition, pursuant to each of the Outstanding Counterparty Notes, the Company has the right to prepay in cash all or part of the principal and accrued interest at any time upon 15 business days’ prior notice, subject to the Counterparty’s conversion right with respect to the contemplated prepayment amount. The Company is required to pay in cash any amounts of principal and accrued interest outstanding at the maturity date of each of the Outstanding Counterparty Notes, which is February 22, 2023 in both instances.

Each of the Outstanding Counterparty Notes is convertible at the Counterparty’s election into shares of common stock at any time prior to February 22, 2023, at a price per share that is 90% of the volume weighted average price of such shares during the twenty (20) trading days preceding the applicable conversion date (the “Discounted Sale Price”), subject to a floor price of \$12.50 per share (the “Conversion Rate Floor Price”). The Conversion Rate Floor Price under each of the Outstanding Counterparty Notes is subject to customary adjustments for certain capital events.

The Counterparty may cause the redemption of the Outstanding Counterparty Notes upon any event of default by the Company. Events of default under the Outstanding Counterparty Notes include, among others, a failure by the Company to convert the applicable note upon proper notice by the Counterparty or pay principal and interest on the applicable note when due; an acceleration of any other indebtedness under the Amended Credit Agreement or other indebtedness of the Company in excess of \$1.0 million; a bankruptcy of the Company; a judgment against the Company in excess of \$1.0 million; a representation or warranty made in the Counterparty SPA and the related transaction documents is materially false or misleading when made; a material breach by the Company of a covenant or other term or condition in the Counterparty SPA and the related transaction documents; the Counterparty SPA and the related transaction documents cease to be effective; the termination or amendment of the Eighth Amendment to the Credit Agreement or the Sixth Amendment to the Royalty Agreement; and the incurrence of a lien on collateral that is not a permitted lien. The Company is required to redeem for cash each of the Outstanding Counterparty Notes upon a change of control of the Company in an amount equal to 101% of the aggregate principal and accrued interest outstanding as of the change of control.

Each of the Outstanding Counterparty Notes also provides the Counterparty with certain rights to acquire additional shares of common stock or other securities or assets of the Company, as applicable, in the event: (i) the Company grants, issues or sells any options, convertible securities or rights to purchase stock, warrants, securities or other property pro rata to the holders of common stock; or (ii) the Company makes certain other distributions to Company stockholders such that, in the case of (i) or (ii), the Counterparty receives, in addition to the shares of common stock otherwise issuable upon conversion of the Outstanding Counterparty Notes, the shares of common stock or other securities or assets, as applicable, that the Counterparty would have been entitled to receive if the Counterparty had converted the Outstanding Counterparty Notes into common stock immediately prior to such event.

The Outstanding Counterparty Notes are secured by the Collateral. The Counterparty has agreed to preserve license rights granted to other customers for any license rights granted prior to a foreclosure. The terms and conditions of the Outstanding Counterparty Notes, if purchased by the Counterparty, are substantially the same as the terms and conditions of the Outstanding Counterparty Notes, except that the "Conversion Rate Floor Price" will be the greater of (x) \$12.50, (y) the closing sale price of the common stock on the trading day preceding the issuance date, and (z) the book value per share of common stock on the trading day immediately preceding the issuance date.

The Company determined that the conversion feature should be accounted for as a stock put option and would be bifurcated from the value of the Outstanding Counterparty Notes and treated as a derivative liability. The initial fair value of the derivative liability was determined to be \$1.7 million. The fair value of this liability will be adjusted to fair market value on a recurring basis. As of September 30, 2016, the fair market value of the 2016 Convertible Note, which was the only Note outstanding at such time, was determined to be \$0.4 million.

On September 29, 2016, the Company and the Counterparty entered into a letter agreement (the "September Counterparty Letter Agreement"). Pursuant to the September Counterparty Letter Agreement, the Counterparty agreed (i) until 11:59 p.m. New York City time on July 1, 2017, to waive any and all rights whatsoever that the Counterparty has or may have under the Counterparty SPA and certain related transaction documents to declare an "Event of Default" under the 2016 Convertible Note as a result of the Company's failure to timely file the March 2016 10-Q or the 2016 10-K (together, the "Exchange Act Filings"); and (ii) that the filing by the Company of the Securities Filings with the SEC will cure any breach of Section 6.3 of the Counterparty SPA as a result of the Company's failure to timely file the Securities Filings with the SEC. As noted above, the Company filed the Exchange Act Filings with the SEC on October 24, 2016.

On July 28, 2016, the Company and the Counterparty entered into two letter agreements. Pursuant to the first letter agreement, the Counterparty agreed to not convert the Notes into shares of the Company's common stock to the extent that such conversion would cause the Counterparty to beneficially own 10% or more of the outstanding shares of the common stock immediately following such conversion (the "Conversion Limit"). Pursuant to such letter agreement, the Counterparty has the right to terminate the Conversion Limit at any time with 75 days' prior written notice to the Company. Pursuant to the second letter agreement, the Counterparty agreed (i) to waive, until 11:59 p.m. New York City time on November 7, 2016, any and all rights whatsoever that the Counterparty had to declare an "Event of Default" under the 2016 Convertible Note as a result of the Company's failure to timely file the March 2016 10-Q; and (ii) that the Company's filing of the March 2016 10-Q with the SEC will cure any breach of Section 6.3(i) of the SPA, as a result of the Company's failure to timely file the March 2016 10-Q with the SEC. As noted above, the Company filed the March 2016 10-Q with the SEC on October 24, 2016.

Under section 6.3 of the Counterparty SPA, the Company is required to, until the date on which the Counterparty has sold all the shares of the Company's common stock into which the Notes are convertible (the "Conversion Shares") and none of the Notes are outstanding, (i) timely file all reports required to be filed with the SEC pursuant to the Exchange Act or the rules and regulations thereunder and (ii) not take any action or file any document (whether or not permitted by the Securities Act or the rules promulgated thereunder) to terminate or suspend the Company's reporting and filing obligations under the Exchange Act or Securities Act, (iii) take all actions necessary to maintain the Company's eligibility to register the Conversion Shares for resale by the Counterparty on Form S-3, and (iv) use its commercially reasonable efforts to take all action as may be required as a condition to the availability of Rule 144 under the Securities Act with respect to the Company's common stock.

Mortgage Loan

In October 2010, Cross Farm entered into the Loan Agreement with First National Bank (formerly known as Metro Bank), pursuant to which First National Bank provided Cross Farm with two mortgage loans in the amounts of \$14.25 million ("First Mortgage") and \$3.75 million ("Second Mortgage"). The proceeds received were used to finance the purchase of land and construction of the Company's corporate headquarters and manufacturing facility in York, Pennsylvania. In connection with the credit agreement, the Company entered into the Metro Bank Amendment pursuant to which the Second Mortgage due October 2020 was repaid. Cross Farm is paying principal and interest on the First Mortgage, with interest at a fixed rate of 6.00%.

The original First National Bank loan documents contain certain customary covenants, including the maintenance of a debt service reserve account in the amount of \$2.4 million, classified as restricted cash on the consolidated balance sheets, which will remain in place until Cross Farm and First National Bank agree on the financial covenants. In addition the Company is required to maintain a cash balance of \$5.0 million inclusive of the \$2.4 million reserve account. The terms of the original First National Bank loan documents allow the Company to use the debt service reserve account to pay monthly debt service on the mortgage loans, so long as the balance in the account is at least \$1.6 million and is replenished to \$2.4 million every six months. The Company is in compliance with its debt covenants as of September 30, 2016. However, there can be no assurance that the Company will be able to maintain the debt service reserve account balance for a period of 12 months from September 30, 2016. Cross Farm may prepay the loan without penalty. The U.S. Department of Agriculture has guaranteed \$8.0 million of the mortgage loan due December 2031. In connection with the First Mortgage, the Company has given First National Bank a lien on the building and real estate and the debt service reserve account.

Commonwealth of Pennsylvania Financing Authority Loan

In December 2010, Cross Farm received a \$2.25 million loan from Keystone Redevelopment Group, LLC (“Keystone”) for land and the construction of its current manufacturing facility. The loan bears interest at a rate of 5.00% per annum, matures in January 2021 and is secured by a third mortgage on the facility. Keystone assigned the loan and mortgage (the “Keystone/CFA Loan”) to the Commonwealth of Pennsylvania Financing Authority. In connection with the Keystone/CFA Loan, Cross Farm entered into an intercreditor agreement by which the Commonwealth of Pennsylvania agreed that it would not exercise its rights in the event of a default by Cross Farm without the consent of Metro Bank, which holds the first mortgage on the facility.

Loan from our Former CEO

On September 30, 2015, the Company obtained a loan in the amount of \$0.6 million from Alan Shortall, the Company’s former Chairman and Chief Executive Officer. During February 2016, the loan was repaid in full including payment of interest to Mr. Shortall at the minimum applicable federal rate, which interest was less than \$0.1 million.

10. Net Loss Per Share

The Company’s net loss per share is as follows:

	Three Months Ended September 30,	
	2016	2015
	(In thousands, except share and per share data)	
Numerator		
Net loss	\$ (17,973)	\$ (25,864)
Denominator		
Weighted average number of shares used to compute basic net loss per share	16,627,517	12,452,799
Effect of dilutive options to purchase common stock	—	—
Weighted average number of shares used to compute diluted net loss per share	16,627,517	12,452,799
Basic and diluted net loss per share	\$ (1.08)	\$ (2.08)

Due to the Company’s net losses, unvested shares of restricted stock (participating securities) totaling 850,345 and 1,063,524 were excluded from the calculation of basic and diluted net loss per share during the three months ended September 30, 2016 and 2015, respectively.

In addition, stock options and warrants (non-participating securities) totaling 1,887,797 and 306,669 during the three months ended September 30, 2016 and 2015, respectively, were excluded from the calculation of diluted net loss per share, as their effect would have been anti-dilutive. Certain of these stock options were excluded solely due to the Company’s net loss position. Had the Company reported net income during the three months ended September 30, 2016 and 2015, these shares would have had an effect of 0 and 0 diluted shares, respectively, for purposes of calculating diluted net income per share. The impact of the potential conversion of 2016 Convertible Note of 2,482,575 diluted shares was also excluded from the calculation of diluted net loss per share for the three months ended September 30, 2016 as their effect would have been anti-dilutive.

11. Contingencies

From time to time, the Company is involved in various legal proceedings, claims, suits and complaints arising out of the normal course of business. Based on the facts currently available to the Company, management believes that these claims, suits and complaints are adequately provided for, covered by insurance, without merit or that it is not probable that an unfavorable outcome will result.

In addition, the Company is or was involved in the following legal proceedings. A former employee, Talbot Smith, who was terminated for cause by Unilife, filed a civil complaint in the United States District Court of the Eastern District of Pennsylvania on August 30, 2013, and an amended complaint on March 5, 2014, alleging that he was wrongly terminated in retaliation for making allegations about the Company's compliance practices. Following the discovery process, Mr. Smith dismissed his claims against the Company with prejudice. In connection with the resolution and dismissal of the action, Mr. Smith agreed to make a payment to the Company to settle counter claims the Company had brought against him. Mr. Smith received no payment as part of the resolution and dismissal of his claims against the Company, his attorney received a reduced portion of her fees from the Company's insurer, and the matter is now concluded.

As previously disclosed, subsequent to the filing of an OSHA complaint by Mr. Smith, we received a subpoena from the staff of the SEC (the "Staff") requesting the Company to provide certain information to the Staff, which is generally consistent with the meritless allegations made by Mr. Smith in his OSHA complaint. In his complaint filed in the United States District Court for the Eastern District of Pennsylvania, Mr. Smith stated that he provided the Staff with information about his allegations in July and August 2012. The Company responded to that subpoena and has received additional subpoenas and requests for information from the Staff, requesting additional information consistent with the first subpoena. The Staff has also requested information about public statements made by the Company's former Chief Executive Officer. The Company has provided the requested information to the Staff.

On May 8, 2016, the Company announced an investigation into violations of the Company's policies and procedures and possible violations of laws and regulations by the Company's former Chief Executive Officer, Alan Shortall, whose employment with the Company ceased on March 11, 2016, and its former Chairman, Jim Bosnjak, who resigned from the Board on August 24, 2015 (the "Investigation"). The Investigation was completed on October 7, 2016, and the Company has reported to the SEC on the Company's findings from the Investigation, has responded to questions from the Staff regarding the findings, and is cooperating fully with the Staff. To date, the SEC has not indicated whether any fines or penalties will be assessed against the Company in relation to these matters. The Company is unable to predict what action the SEC or other regulatory authority may take, if any, in relation to these matters or the impact, if any, of any such action on the Company's business, operations, cash flows and/or financial condition. If any fines or penalties are assessed against the Company, they may be material.

As previously disclosed, on January 8, 2014, the Company was served with a derivative complaint filed in the Delaware Chancery Court (the "Court") by Cambridge Retirement System ("Cambridge"), a purported stockholder of the Company, against its then-current Board of Directors to recover allegedly "excessive and wasteful" compensation paid to the non-executive directors since 2010. In June, 2014, pursuant to the Company's motion to dismiss the complaint, the Court dismissed Cambridge's complaint with respect to the directors' equity grants, but denied the motion with respect to their cash compensation. The Company filed an answer to the remaining claims in July 2014 and, in June 2015, the Company and Cambridge entered into a Memorandum of Understanding ("MOU") agreeing to the basic terms of a non-monetary settlement of the action.

On March 18, 2016, Cambridge agreed to voluntarily dismiss its derivative complaint. No compensation in any form was provided to either Cambridge or its counsel in exchange for its agreement to voluntarily dismiss the lawsuit. Because Cambridge agreed to voluntarily dismiss the lawsuit, the MOU has become null and void and of no further legal effect. On March 18, 2016, the Court entered a stipulated order regarding notice of the proposed dismissal of all claims in the derivative action (the "Proposed Dismissal Order"). On April 18, 2016, the Court entered that stipulation as an order, dismissing the case with prejudice.

On September 14, 2015, Unilife Medical Solutions Inc., a subsidiary of the Company ("UMSI") was served with a complaint filed in the Superior Court of the State of Connecticut by Bidel, Inc. ("Bidel") seeking (1) to temporarily enjoin UMSI from entering into a transaction that would jeopardize the Company's ability to perform its obligations under the Customization and Commercial Supply Agreement effective April 8, 2013 (as amended, the "First Bidel Agreement") between Bidel and UMSI; and (2) damages under the Connecticut Unfair Trade Practices Act. Bidel alleged that UMSI had engaged in unfair and deceptive trade practices by purportedly misrepresenting its ability and willingness to satisfy its obligations under the First Bidel Agreement and requesting additional payments from Bidel to satisfy the Company's obligations. Additionally, Bidel filed a demand for arbitration with the American Arbitration Association (AAA) asserting that UMSI had breached its obligations relating to the timing and scope of its performance under the First Bidel Agreement. The Company filed counterclaims in the arbitration for commercial disparagement and breach of the confidentiality provisions of the agreement.

On September 2, 2016, Bidel, the Company and UMSI entered into an Asset Purchase and License Agreement (the “Second Bidel Agreement”) which provides: (a) for the termination of the First Bidel Agreement; (b) for the grant of an exclusive license for a six-month term to the intellectual property rights related to the Unilife mixing device; (c) a six-month term during which Bidel can exercise an option (the “Option”) to purchase certain assets associated with the First Bidel Agreement for \$1.5 million (the “Potential Asset Sale”) and extend Bidel’s license, for fees based on intellectual prosecution and maintenance costs determined on an annual basis; (d) dismissal, with prejudice, of all active proceedings in connection with the litigation and arbitration proceedings pending between Bidel and UMSI. Under the Second Bidel Agreement, each party also releases the other party of all liability, waives all claims with prejudice, and forever holds the other party harmless from any damages arising out of relating to the First Bidel Agreement. Bidel and UMSI each paid their respective attorneys’ fees and UMSI paid no monetary amount to Bidel in connection with this resolution.

On March 24, 2016, Edward Fine filed a complaint against the Company and Unilife Medical Solutions Limited (“UMSL”) in the Superior Court of New Jersey. The complaint alleges that the Company and UMSL are in breach of contract and have been unjustly enriched as a result of UMSL’s failure to pay certain required payments under a consultancy agreement between Mr. Fine and UMSL. Pursuant to the complaint, Mr. Fine is seeking monetary damages in the amount of \$288,000 in the aggregate. The Company believes that Mr. Fine’s claims and demands for relief are wholly without merit and the Company is vigorously defending the action. On August 15, 2016, we filed an Answer, Affirmative Defenses and Counterclaims, wherein we asserted counterclaims against Mr. Fine for fraud, civil conspiracy, unjust enrichment, breach of contract, and breach of the implied covenant of good faith and fair dealing arising out of Mr. Fine’s role in certain previously disclosed transactions involving Mr. Fine and Jim Bosnjak, the Company’s former Chairman of the Board. This action is currently in a 450-day discovery period which commenced on July 29, 2016.

On May 26 and 27, 2016, two putative class actions were filed in the United States District Court for the Southern District of New York alleging that in violation of Rule 10b-5 and Section 20(a) of the Exchange Act, the Company and six individual defendants made false and/or misleading statements and/or failed to disclose: (1) that the Company’s former CEO and former Chairman of the Board of Directors had violated the Company’s policies and procedures and had engaged in violations of law and regulations; (2) that the Company lacked adequate internal controls over accounting and financial reporting; (3) that, as a result, the Company would be unable to file its Quarterly Report on Form 10-Q for the period ended March 31, 2016 by the prescribed filing deadline; and (4) that, as a result of the foregoing, the Company’s financial statements, as well as its statements about the Company’s business, operations, and prospects, were false and misleading and/or lacked a reasonable basis. The putative class actions were brought on behalf of purchasers of the Company’s securities between February 3, 2014 and May 23, 2016. On August 24, 2016, the Court consolidated the two actions, appointed lead plaintiffs and lead counsel, and set a deadline of October 24, 2016 for Plaintiffs to file an amended complaint. The plaintiffs filed an amended complaint on October 24, 2016 expanding the class to purchasers of the Company’s securities between November 9, 2011 and July 28, 2016, dropping three of the original individual defendants as named defendants and making additional allegations related to matters the Company disclosed in connection with the Investigation. The Company intends to vigorously contest this lawsuit.

On July 11, July 28, and August 1, 2016, respectively, derivative complaints were filed in the Court of Common Pleas in York County, Pennsylvania against 11 current or former directors and/or officers, alleging (i) breach of their fiduciary duties, (ii) unjust enrichment, (iii) abuse of control, (iv) gross mismanagement, and (v) corporate waste. The complaints allege, among other things, that the individual defendants breached the fiduciary duties they owed to the Company by (1) grossly mismanaging the Company and perpetuating a variety of self-serving schemes to benefit themselves and other interested parties and (2) making and/or causing the Company to make false/misleading statements or omissions of fact in its public disclosures. The complaints further allege that as a result of this alleged conduct, the Company will lose and expend millions of dollars. The Company intends to vigorously contest these lawsuits.

On August 17, 2016, Kahle Automation, S.r.l. (“Kahle”) filed a complaint against Unilife Medical Solutions, Inc. (“UMS”) in the United States District Court for the District of New Jersey. The complaint alleges that UMS breached contracts with Kahle for Kahle’s supply of automation systems for UMS’ Nexus and Finesse product lines. Kahle seeks monetary damages of \$4.2 million which includes alleged damages that we believe are not recoverable, such as \$0.9 million for bank fees, and \$0.8 million for lost profits. Kahle also seeks injunctive relief enjoining UMS from using the Nexus System and requiring UMS to take delivery of work in process related to the Finesse System. UMS disputes Kahle’s allegations that UMS terminated its agreement with Kahle for the Finesse System. We intend to defend ourselves vigorously against these claims.

The Company believes that depending on the outcome, certain of these matters may have a material impact to the Company or its business.

12. Revenue

The Company recognized \$1.7 million and \$3.2 million of revenue during the three months ended September 30, 2016 and 2015, respectively.

During the three months ended September 30, 2016, two customers accounted for 54% and 41% of consolidated revenue, respectively. During the three months ended September 30, 2015, four customers accounted for 25%, 24%, 24% and 20% of consolidated revenue, respectively.

2016

During the three months ended September 30, 2016, the Company recognized \$0.4 million of revenue, related to substantive milestones, as follows:

The Company recognized \$0.4 million of revenue during the three months ended September 30, 2016 pursuant to a master services and supply agreement with a customer related to substantive milestones that were completed and accepted. This agreement provides for certain customization and development activities for a drug delivery system to be performed for the customer and provides for payments to be made upon the completion of agreed-upon substantive milestones. An initial up-front payment of \$1.1 million was determined to be non-substantive and is being recognized on a straight-line basis over the expected term of the agreement. The remaining milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the three months ended September 30, 2016 are as follows:

- \$0.4 million for development and delivery of components for a human factor study;

The remaining substantive milestones as of September 30, 2016 are as follows:

- \$0.4 million for completion of testing of assembly equipment;
- \$0.3 million for completion of filling process of clinical devices;
- \$0.4 million for delivery of containers for the filling process; and
- \$0.3 million for delivery of devices for clinical studies.

During the three months ended September 30, 2016, the Company recognized \$1.2 million in revenue related to services rendered on a time and materials basis, proportional performance method, the completed contract method and/or straight line basis over the requisite service period pursuant to customer agreements to provide various customization and development services.

On December 31, 2015, the Company entered into an exclusivity agreement (the "Exclusivity Agreement") with Amgen Inc. (the "Counterparty"). Pursuant to the Exclusivity Agreement, the Counterparty paid to the Company a non-refundable \$15.0 million license fee (the "First License Fee"). The Company and the Counterparty then entered into a License Agreement on February 5, 2016 (the "First License Agreement") to further define the license rights set forth in the Exclusivity Agreement. Furthermore on February 22, 2016, the Company granted the Counterparty exclusive rights to the Company's wearable injectors within select drug classes for use with certain assets, while preserving rights the Company previously granted to other customers. The Company has also granted to the Counterparty non-exclusive rights to all of the Company's proprietary delivery systems within the therapeutic areas of oncology, inflammation, bone health, nephrology, cardiovascular and neuroscience. The Counterparty paid to the Company an additional non-refundable \$20.0 million fee (the "Second License Fee") in consideration for such licenses. During the three months ended September 30, 2016, the Company began development work on wearable injector devices related to the First License Agreement, and recognized \$0.1 million in license revenue relating to the First License Fee. The Company will recognize the First License Fee ratably over the life of patents relating to the Company's wearable injectors, which is expected to be through 2032.

2015

During the three months ended September 30, 2015, the Company recognized \$1.8 million of revenue related to substantive milestones, as follows:

The Company recognized \$0.5 million of revenue during the three months ended September 30, 2015 pursuant to a feasibility agreement with a customer related to substantive milestones that were completed and accepted. This agreement provides for certain customization and development activities for a drug delivery system to be performed for the customer and provides for payments to be made upon the completion of agreed-upon substantive milestones. An initial up-front payment of \$0.1 million was determined to be non-substantive and is being recognized on a straight line basis over the expected term of the agreement. The remaining milestones were d

etermined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the three months ended September 30, 2015 are as follows:

- \$0.5 million for development and delivery of additional human factor stimuli and a report on updated product requirements;

The remaining substantive milestones as of September 30, 2015 were as follows:

- \$1.2 million for development and delivery of semi-functional prototypes and related feasibility, product requirement, and risk management reports.

The Company recognized \$0.6 million of revenue during the three months ended September 30, 2015 pursuant to a master services and supply agreement with a customer related to substantive milestones that were completed and accepted. This agreement provides for certain customization and development activities for a drug delivery system to be performed for the customer and provides for payments to be made upon the completion of agreed-upon substantive milestones. An initial up-front payment of \$1.1 million was determined to be non-substantive and is being recognized on a straight-line basis over the expected term of the agreement. The remaining milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the three months ended September 30, 2015 are as follows:

- \$0.6 million for development and delivery of a complete system layout;

The remaining substantive milestones as of September 30, 2015 are as follows:

- \$0.3 million for development and delivery of components for a human factor study;
- \$0.6 million for development and delivery of feasibility devices for testing;
- \$0.6 million for development and delivery of a clinical production process;
- \$0.4 million for development and delivery of components for a human factor study;
- \$0.4 million for completion of testing of assembly equipment;
- \$0.3 million for completion of filling process of clinical devices;
- \$0.4 million for delivery of containers for the filling process; and
- \$0.3 million for delivery of devices for clinical studies.

The Company recognized \$0.3 million of revenue during the three months ended September 30, 2015 pursuant to a feasibility agreement with a customer related to substantive milestones that were completed and accepted. This agreement provides for certain customization and development activities for a drug delivery system to be performed for the customer and provides for payments to be made upon the completion of agreed-upon milestones. An initial up-front payment of \$0.5 million was determined to be non-substantive and is being recognized on a straight-line basis over the expected term of the agreement. The remaining milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the three months ended September 30, 2015 are as follows:

- \$0.3 million for development and delivery of a summary report related to testing and documentation activities.

There are no remaining substantive milestones under this agreement.

The Company recognized \$0.4 million of revenue during the three months ended September 30, 2015 pursuant to a master services and supply agreement with a customer related to substantive milestones that were completed and accepted. This agreement provides for certain customization and development activities for a drug delivery system to be performed for the customer and provides for payments to be made upon the completion of agreed-upon substantive milestones. An initial up-front payment of \$1.0 million was determined to be non-substantive and is being recognized on a straight-line basis over the expected term of the agreement. The remaining milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the three months ended September 30, 2015 are as follows:

- \$0.4 million for development and delivery of feasibility devices for testing;

The remaining substantive milestones as of September 30, 2015 are as follows:

- \$0.6 million for delivery of design transfer for the Device and the related filling equipment and fixtures; and
- \$0.3 million for commissioning of the pilot line.

During the three months ended September 30, 2015, the Company recognized \$1.4 million in revenue related to services rendered on a time and materials basis, proportional performance method and/or straight line basis over the requisite service period pursuant to customer agreements to provide various customization and development services.

13. Departure of Officers; Appointment of Officers

On July 25, 2016, the Company's employment of Mark Iampietro as the Company's Vice President of Quality and Regulatory Affairs and Chief Compliance Officer was ended by the Company without cause. Pursuant to the Employment Agreement, dated November 6, 2014, by and between the Company and Mr. Iampietro, Mr. Iampietro is entitled to (i) receive \$252,000 over a period of 12 months following the termination, which amount represents Mr. Iampietro's base salary as of the termination, (ii) continue to receive group health benefits for a period of 12 months following the termination, and (iii) receive \$88,200 over a period of 12 months following the termination, which amount represents the amount of the bonus earned by and paid to Mr. Iampietro in 2015 as well as the target bonus for which Mr. Iampietro was eligible to earn in 2016. In addition, all of Mr. Iampietro's outstanding and unvested options and other stock-based awards immediately vested.

On July 28, 2016:

- the Board appointed Michael E. Kamarck to serve as a member of the Board;
- the Board appointed Ian Hanson as the Company's Chief Operating Officer in addition to his roles as the Company's Senior Vice President;
- due to results of the Investigation, Dennis P. Pyers was removed from his position as the Company's Senior Vice President, Controller, Treasurer and Chief Accounting Officer and was appointed as the Company's Senior Advisor, Special Projects; and
- the Board appointed David Hastings as the Company's Chief Accounting Officer and Treasurer in addition to his roles as the Company's Senior Vice President and Chief Financial Officer;
- the Board appointed Stephanie Walters as Senior Vice President, General Counsel and Secretary; and
- the Board appointed Molly Weaver, Ph.D., as Vice President of Quality and Regulatory Affairs and Chief Compliance Officer.

On October 27, 2016:

- William Galle notified the Company that he was not seeking re-appointment to the Board and was therefore resigning from the Board effective as of the date of the Company's 2016 annual stockholder meeting.

On October 28, 2016:

- the Board appointed Rosemary A. Crane and Duane DeSisto to serve as members of the Board.

14. Fair Value Measurements

The Company categorizes its assets and liabilities measured at fair value into a fair value hierarchy that prioritizes the inputs used in pricing the asset or liability. The three levels of the fair value hierarchy are as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

The levels in the fair value hierarchy within which a fair value measurement in its entirety falls is based on the lowest level input that is significant to the fair value measurement in its entirety.

The following table presents the Company's liabilities that are measured at fair value on a recurring basis for the periods presented:

	Total Fair Value Measurements	Basis of Fair Value Measurement		
		Quoted Market Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
(In thousands)				
September 30, 2016:				
Royalty agreement liability	\$ 5,388	\$ —	\$ —	\$ 5,388
Warrant liability	1,810	—	—	1,810
Derivative liability	353	—	—	353
June 30, 2016:				
Royalty agreement liability	\$ 5,120	\$ —	\$ —	\$ 5,120
Warrant liability	3,351	—	—	3,351
Derivative liability	347	—	—	347

The following table presents the changes in the fair value of the level 3 financial instruments for the three months ended September 30, 2016.

	Royalty Agreement Liability	Warrant Liability	Derivative Liability
June 30, 2016	\$ 5,120	\$ 3,351	\$ 347
Cash payments	(6)	—	—
Increase (decrease) in liability	274	(1,541)	6
September 30, 2016	<u>\$ 5,388</u>	<u>\$ 1,810</u>	<u>\$ 353</u>

Following is a description of the valuation methodologies used to measure the royalty agreement liability, the warrant liability, and the derivative liability. There have been no changes in the methodology used during the three months ended September 30, 2016.

The fair value of the royalty agreement liability is based on a discounted cash flow methodology under the income approach based on the present value sum of payments expected to be made in the future. The fair value is estimated by applying a risk adjusted discount rate to the expected royalty payment stream. These fair value estimates are most sensitive to changes in the payment stream and royalty rates.

The fair value of the warrant liability is based on a Black-Scholes valuation. The fair value estimates are most sensitive to changes in the Company's share price.

The fair value of the derivative liability is based on the average of a Monte Carlo model and a lattice model. The fair value estimates are most sensitive to changes in the Company's share price.

Other Financial Instruments

The carrying amount of the Company's cash equivalents, which includes certificates of deposit, accounts receivable, accounts payable and accrued expenses approximate fair value due to the short term maturities of these items. The estimated fair value of the Company's debt approximates its carrying value based upon the rates that the Company would currently be able to receive for similar instruments of comparable maturity.

15. Sublease

In June 2016, we subleased a portion (the “Subleased Portion”) of our King of Prussia offices. During the term of the sublease, which commenced on October 1, 2016 and will end on March 31, 2019, the Company will receive an aggregate of approximately \$1.3 million in rent with respect to the Subleased Portion. During the same time period, the Company will be obligated under the Company’s lease agreement relating to our King of Prussia offices to pay an aggregate of approximately \$1.9 million in rent with respect to the Subleased Portion. Assuming the sublessee exercises its renewal option, the Company will receive approximately an additional \$1.9 million over the renewal term of April 1, 2019 through June 30, 2022 and the Company will be obligated under the Company’s lease agreement relating to the King of Prussia Facility to pay an aggregate of approximately \$2.5 million over the same time period. The Company ceased using the Subleased Portion as of July 20, 2016.

The Company recognized a liability associated with the subleased portion under a cease-use date approach since the subleased portion did not have any future economic benefit to the Company. The liability was measured and recognized at fair value at cease-use date and the fair value was determined based on the present value of the remaining lease obligations, adjusted for the effects of deferred items recognized under the lease, and reduced by sublease rentals as noted above. In determining the fair value of the liability, the Company assumed that the renewal term would be exercised by the sublessee. The amount of the non-cash charge recorded to record the fair value of the liability was \$0.7 million. The expected cash flows used to estimate the fair value of the liability was discounted using an interest rate that equates to a risk-free rate adjusted for the effect of the Company’s credit standing. The fair value measurement was categorized as Level 3 based on the fair value hierarchy under ASC Topic 820 – *Fair Value Measurements and Disclosures*. Additionally, the Company evaluated certain fixed assets related to Subleased Portion and determined that the remaining useful life to the Company had changed and accelerated all remaining depreciation to these assets. This expense of \$0.6 million was recorded in depreciation and amortization. The Company expensed all other costs related to the sublease as incurred.

Over the life of the expected term of the sublease, the Company expects to incur approximately \$0.3 million in expense to accrete the value of the liability based on the difference between the net cash flows and present value of these cash flows.

The charges, except as noted above, were included in selling, general and administrative expenses. The following table summarizes the liability and costs paid or settled in connection with the sublease, along with total charges expected to be incurred and cumulative charges incurred to date:

	<u>Sublease Costs</u>
	<u>(In thousands)</u>
Liability balance as of June 30, 2016	\$ —
Initial liability measurement	909
Costs incurred and charges to expenses	10
Costs paid or settled	(118)
Liability balance as of September 30, 2016	<u>\$ 801</u>
Total charges expected to be incurred	<u>\$ 1,599</u>
Cumulative charges incurred to date	<u>\$ 1,303</u>

16. Related Party Transactions

Loan from Mr. Shortall

On September 30, 2015, the Company obtained a loan in the amount of \$600,000 from Alan Shortall, the Company’s former Chairman and Chief Executive Officer. During February 2016, the loan was repaid in full including payment of interest to Mr. Shortall at the minimum applicable federal rate, which interest was less than \$2,000.

Bosnjak Mortgage Correspondence

In July 2015, Mr. Shortall and Mr. Bosnjak, without authorization from or knowledge of the Company or its Board, caused to be transmitted to a mortgage broker for Mr. Shortall from Mr. Bosnjak correspondence that contained inaccurate statements about the Company’s financial support for Mr. Shortall’s purchase of and relocation to a new home. The investigation into the matters described in this paragraph did not identify any financial loss to the Company and the Company has corrected the inaccurate statements to the mortgage broker.

Shortall Fund Transfers

Mr. Shortall deposited \$2,264,475 of his own funds into the Company's bank account on June 29, 2015 and then caused the Company to disburse from the Shortall Funds \$1,351,553 to third parties to complete Mr. Shortall's purchase of his new home on July 23, 2015, and the remainder back to himself on July 28, 2015.

For the three months ended September 30, 2015, under Mr. Shortall's direction, the Company accepted a check from Mr. Shortall in the aggregate amount of approximately \$6,000 and disbursed the same amount of funds to Mr. Shortall's designee but did not deposit such check from Mr. Shortall until nineteen days after the Company's disbursement of the funds. The Company believes such transaction constituted a loan from the Company to Mr. Shortall. There were no such transactions for the three month period ended September 30, 2016.

Bosnjak Loan Payments and Unreimbursed Personal Expenses

For the three months ended September 30, 2015, Mr. Shortall caused approximately \$12,000 in Company funds to be transmitted to a third party on behalf of Mr. Bosnjak which had no business purpose for the Company. The Company believes that these payments constituted loans from the Company to Mr. Bosnjak, and the Company is evaluating potential actions to recover these funds. The collection of such amounts is uncertain and the Company has recorded approximately \$12,000 as Selling, General and Administrative Expense in the three months ended September 30, 2015. There were no such transactions for the three month period ended September 30, 2016.

For the three months ended September 30, 2015, Mr. Shortall caused the Company to pay for personal expenses of which approximately \$500, was not repaid to the Company (the "Unreimbursed Personal Expenses"). The Company believes the Unreimbursed Personal Expenses constituted loans from the Company to Mr. Shortall, and the Company has demanded repayment of the Unreimbursed Personal Expenses. The collection of such amounts is uncertain and the Company has recorded approximately \$500 as Selling, General and Administrative Expense in the three months ended September 30, 2015. There were no such transactions for the three month period ended September 30, 2016.

Advanced Withholding Payments

In July 2015, in connection with the vesting of restricted shares of the Company's common stock, the Company paid associated withholding taxes on behalf of two executive officers, its Vice President of Quality and Regulatory Affairs and Chief Compliance Officer and its former President and Chief Operating Officer, in an aggregate amount of approximately \$126,000 prior to being reimbursed by such executive officers. Such executive officers repaid the Company in full within a range of 18 to 28 days from the date of the withholding payment and before September 30, 2015. The Company believes such advances constituted loans. There were no such loans during the three months ended September 30, 2016.

17. Subsequent Events

On October 24, 2016, the Company Parties and the Counterparty entered into the October Counterparty Letter Agreement, pursuant to which the Company Parties agreed to issue to the Counterparty on October 24, 2016, in accordance with the terms and conditions of the Counterparty SPA and the October Counterparty Letter Agreement, the Accelerated Convertible Note in the initial principal amount of \$10.0 million plus a \$0.6 million Financing Fee, for an aggregate initial principal amount of \$10.6 million. In consideration for issuing the Accelerated Convertible Note, the Counterparty paid to the Company \$10.0 million on October 24, 2016.

Pursuant to the October Counterparty Letter Agreement, the remaining \$5.0 million portion of the 2017 Convertible Note will continue to be issuable in January 2017 by the Company Parties to the Counterparty in accordance with the terms and conditions of the Counterparty SPA. The Lender has the right to consent to the issuance of such \$5.0 million portion of the 2017 Convertible Note. There can be no assurance as to when or if the Counterparty will purchase all or any part of the remaining portion of the 2017 Convertible Note and/or the 2018 Convertible Note, or if the Lender will consent to the issuance of the remaining portion of the 2017 Convertible Note. For additional information regarding the October Counterparty Letter Agreement and the Accelerated Convertible Note, see note 3 "Liquidity".

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

Cautionary Note Regarding Forward-Looking Information

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. This discussion and analysis includes certain forward-looking statements that involve risks, uncertainties and assumptions. You should review the “Risk Factors” section of the 2016 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by such forward-looking statements.

Certain statements in this Quarterly Report on Form 10-Q may constitute forward looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements. These forward-looking statements are based on management’s beliefs and assumptions and on information currently available to our management. Our management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. We do not undertake any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In addition, forward-looking statements are subject to certain risks and uncertainties that could cause actual results, events and developments to differ materially from our historical experience and our present expectations or projections. These risks and uncertainties include, but are not limited to, those described in “Item 1A. Risk Factors” in the 2016 10-K and those described from time to time in other reports, which we file with the SEC.

Overview

We are a designer, manufacturer, and supplier of innovative injectable drug delivery systems that can enhance and differentiate the injectable products of our pharmaceutical and biotechnology customers. We believe our products are differentiated from conventional products, with innovative features and functionality designed to optimize the safe, simple, and convenient administration of injectable therapies. The majority of our products are designed for sale directly to pharmaceutical and biotechnology companies who are expected to supply them as drug-device combination products, pre-filled and ready for administration by end-users, such as patients or health-care providers. We customize products within each of our platforms to address specific customer, therapy, patient and/or commercial requirements.

Although we have a broad portfolio of proprietary product platforms, we are now focusing our business on our wearable injector products. We expect that by focusing primarily on active and new customer programs in our portfolio of wearable injector systems, we will improve our operating efficiencies and better position the Company to take advantage of commercial opportunities within the fast-growing market for wearable injectors. Our wearable injector customers include Amgen Inc., MedImmune LLC (“MedImmune”), and Sanofi S.A. (“Sanofi”).

Investigation

On May 8, 2016, the Company announced an investigation into violations of the Company’s policies and procedures and possible violations of law and regulation by the Company’s former Chief Executive Officer, Alan Shortall, whose employment with the Company ceased on March 11, 2016, and its former Chairman, Jim Bosnjak, who resigned from the Company’s Board of Directors (the “Board”) on August 24, 2015 (the “Investigation”). The Board established a Special Committee to oversee the Investigation. Independent counsel conducted the Investigation with the assistance of an advisory firm with forensic accounting expertise. The Investigation was completed on October 7, 2016 and no material financial loss was identified.

Management and Board Changes

On July 25, 2016, the Company’s employment of Mark Iampietro as the Company’s Vice President of Quality and Regulatory Affairs and Chief Compliance Officer was ended by the Company without cause.

On July 28, 2016:

- the Board appointed Michael E. Kamarck to serve as a member of the Board;
- the Board appointed Ian Hanson as the Company’s Chief Operating Officer in addition to his roles as the Company’s Senior Vice President;

- due to results of the Investigation, Dennis P. Pyers was removed from his position as the Company's Senior Vice President, Controller, Treasurer and Chief Accounting Officer and was appointed as the Company's Senior Advisor, Special Projects;
- the Board appointed David Hastings as the Company's Chief Accounting Officer and Treasurer in addition to his roles as the Company's Senior Vice President and Chief Financial Officer;
- the Board appointed Stephanie Walters as Senior Vice President, General Counsel and Secretary; and
- the Board appointed Molly Weaver, Ph.D., as Vice President of Quality and Regulatory Affairs and Chief Compliance Officer.

On October 27, 2016:

- William Galle notified the Company that he was not seeking re-appointment to the Board and was therefore resigning from the Board effective as of the date of the Company's 2016 annual stockholder meeting.

On October 28, 2016:

- the Board appointed Rosemary A. Crane and Duane DeSisto to serve as members of the Board.

Investigation and Litigation Related to the Investigation

The Company has reported the final results of the Investigation to the SEC and to The NASDAQ Stock Market LLC ("NASDAQ"), and the Company continues to cooperate fully with the SEC with respect to the SEC's ongoing investigation. The SEC or other external parties could request further documents and information from the Company. The Company and certain of its current and former directors and officers have also been named as defendants in a number of lawsuits filed in connection with the Investigation. For information concerning the SEC's ongoing investigation and such lawsuits, see Part II, Item 1. "Legal Proceedings" of this September 2016 10-Q.

Matters Relating to NASDAQ and Our Common Stock and ASX and our CDIs

The filing of the Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (the "March 2016 10-Q") and the Company's Annual Report on Form 10-K for fiscal year 2016 (the "2016 10-K") were delayed as a result of the Investigation. As a result of such delay, on May 17, 2016 and September 19, 2016, the Company received a notice from the Listing Qualifications department of NASDAQ stating that, because the Company had not yet filed the March 2016 10-Q and the 2016 10-K, respectively, the Company was no longer in compliance with NASDAQ Listing Rule 5250(c)(1), which requires listed companies to timely file all required periodic financial reports with the SEC. On September 8, 2016, NASDAQ granted the Company an exception until November 7, 2016 to regain compliance with NASDAQ Listing Rule 5250(c)(1). The Company filed the March 2016 10-Q and the 2016 10-K on October 24, 2016. On October 27, 2016, the Company received a notice from the Listing Qualifications department of the NASDAQ that the Company had regained and was in compliance with NASDAQ Listing Rule 5250(c)(1).

On October 17, 2016, the Company received a notice from the Listing Qualifications department of NASDAQ stating that, because the Company did not maintain a minimum Market Value of Listed Securities ("MVLS") of \$50,000,000 for the last 30 consecutive business days, the Company was no longer in compliance with NASDAQ Listing Rule 5450(b)(2)(A).

The Company has been provided a period of 180 calendar days, or until April 17, 2017, to regain compliance with the minimum MVLS listing requirement. If at any time on or before April 17, 2017, the MVLS of the Company's common stock closes at \$50,000,000 or more for a minimum of 10 consecutive business days, NASDAQ will provide the Company with written confirmation that the Company has achieved compliance with the minimum MVLS listing requirement and the matter will be closed.

In the event that the Company does not regain compliance with the minimum MVLS listing requirement on or before April 17, 2017, NASDAQ will provide the Company with written notification that its securities are subject to delisting. At that time, the Company would be permitted to appeal the delisting determination to a NASDAQ Hearings Panel or apply to transfer its common stock to The NASDAQ Capital Market (provided that it satisfied the requirement for continued listing on that market).

The Company was also required to file audited financial statements with the Australian Securities Exchange (the "ASX") no later than September 30, 2016 (the "ASX Deadline"). The Company was not able to file such audited financial statements by the ASX Deadline. As a result, pursuant to ASX rules, trading in the Company's CDIs on the ASX was to be suspended prior to the opening of trading on the ASX on October 3, 2016, however, the ASX accepted the Company's request for an immediate voluntary suspension of trading and as such, ASX halted trading of the Company's CDIs on the ASX prior to the opening of trading on September 30, 2016 in Australia. As a result of the Company's filing of audited financial statements with the ASX on October 24, 2016, trading of the Company's CDIs on the ASX has resumed.

Recent Developments

On October 24, 2016, the Company Parties and the Counterparty entered into a letter agreement (the “October Counterparty Letter Agreement”), pursuant to which the Company Parties agreed to issue to the Counterparty on October 24, 2016, in accordance with the terms and conditions of the Counterparty SPA and the October Counterparty Letter Agreement, the Accelerated Convertible Note in the initial principal amount of \$10.0 million plus a \$0.6 million financing fee (the “Financing Fee”), for an aggregate initial principal amount of \$10.6 million. In consideration for issuing the Accelerated Convertible Note, the Counterparty paid to the Company \$10.0 million on October 24, 2016.

Pursuant to the October Counterparty Letter Agreement, the remaining \$5.0 million of the 2017 Convertible Note will continue to be issuable in January 2017 by the Company Parties to the Counterparty in accordance with the terms and conditions of the Counterparty SPA. The Lender has the right to consent to the issuance of such \$5.0 million portion of the 2017 Convertible Note. There can be no assurance as to when or if the Counterparty will purchase all or any part of the remaining portion of the 2017 Convertible Note and/or the 2018 Convertible Note, or if the Lender will consent to the issuance of the remaining portion of the 2017 Convertible Note.

Key Factors Affecting Performance and Financial Condition

We are party to several agreements with our customers, including customers with whom we have entered into customization, development and/or supply agreements. The customization, industrialization and development fees and other payments received from customers in connection with these agreements and development programs accounted for the majority of our revenue during the three months ended September 30, 2016.

Longer customer development timelines and increases in capital expenses and headcount have impacted us from a liquidity standpoint. Historically, we have funded our operations primarily from a combination of term loans, equity issuances, borrowings under our bank mortgages, and payments from various customers. See “Liquidity and Capital Resources Discussion” below.

Revenue

Our revenue is currently generated from customization, industrialization, development and licensing fees (many of which are recognized on the milestone basis of accounting). Customization, industrialization, development and licensing fees accounted for substantially all of our consolidated revenue for the three months ended September 30, 2016. We expect that the Company’s revenue will continue to fluctuate on a quarter to quarter basis.

Operating Expenses

Our operating expenses are decreasing primarily as a result of the cost reduction initiatives put in place in fiscal year 2016 and our strategic decision to focus primarily on our wearable injector customers. Additionally, during the three months ended September 30, 2016, we reduced our headcount by approximately 10 employees. Such headcount reductions are expected to reduce annual operating costs by approximately \$0.6 million. We do not believe that these cost reduction initiatives will negatively impact our ability to serve our customers. The operating expenses decrease is partially offset by an increase in legal and professional fees incurred in connection with the Investigation.

Significant Developments in the Industry

We believe that our existing wearable injector contracts could provide significant revenue growth in relation to prior periods. Known trends in the industry that we believe will have a material favorable impact on our revenue include a shift in the focus of large pharmaceutical and biotechnology companies’ product development activities to biologic therapies, an emphasis within health-care providers to patient self-administration and a growing demand for passive safety for injectable drug delivery. There has been a marked shift in the product development activities of large customers toward biologic therapies, and the majority of therapies in the pipeline of large pharmaceutical and biotechnology companies are complex biologic therapies. The characteristics of many of these therapies (including, for example, large dose volumes and increased viscosity) necessitates administration by injection using innovative injectable drug delivery systems such as our products. We believe that we are well-positioned to meet what we expect to be a growing demand for innovative injectable drug delivery systems in light of the focus on biologic therapies. Concurrently with the shift toward biologic therapies is an emphasis towards patient self-administration. Patient self-administration is viewed as a growing trend in order to reduce demand pressure on the health-care system as well as reducing costs, especially for treatment of chronic illnesses. Devices suitable for self-administration of injectable therapies need to be safe and intuitive to use. We believe that our products are well suited for safe and intuitive patient self-administration of injectable therapies.

Critical Accounting Policies and Estimates

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America. This requires management to make certain estimates, judgments and assumptions that could affect the amounts reported in the consolidated financial statements and accompanying notes.

Our critical accounting policies and estimates are described in Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates” of the 2016 10-K. There have been no changes in critical accounting policies in the current year from those described in the 2016 10-K.

Recently Issued Accounting Pronouncements

See note 4 “Summary of Significant Accounting Policies — Recently Issued Accounting Pronouncements” to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

Basis of Presentation

Revenue

We derive revenue primarily from industrialization and development programs with our customers and licensing agreements. The agreements with our customers generally provide for fees to be paid to us for providing specific products or services. Certain of these agreements provide for fees to be paid upon completion of certain agreed-upon milestones. In instances where these milestones are substantive, we recognize revenue when these agreed-upon substantive milestones have been completed and there is no further performance obligation related to the substantive milestone. Certain of our agreements provide for fees to be paid for specific services to be rendered or the provision of certain deliverables, and we recognize revenue upon completion of the related service or deliverable. Certain of our agreements provide for fees to be paid on an ongoing basis over the life of the agreement for agreed-upon services, and we recognize revenue ratably over the requisite service period. We also recognize revenue on certain agreements under the completed contract method and proportional performance method.

Operating expenses

Operating expenses primarily include costs related to research and development, selling, general and administrative expenses, as well as depreciation and amortization expense.

Research and development costs

Research and development costs consist primarily of payroll and related personnel expenses (including share-based compensation expense), fees paid to external service providers, costs of materials, components and supplies, costs for facilities, tooling and equipment and costs related to customization and development service arrangements and developing prototype products and samples used for various evaluation, testing and related activities for existing and potential customers.

Selling, general and administrative costs

Selling, general and administrative costs include corporate payroll and related benefit costs (including share-based compensation expense), marketing and commercial development costs, quality assurance and regulatory costs, accounting and financial related costs, information and technology costs, legal and professional fees, and corporate facility costs.

Depreciation

Depreciation is calculated on a straight-line basis over the estimated useful lives of the related assets, which range from 40 years for our York, Pennsylvania facility to 2 to 15 years for machinery, equipment, furniture and software and the lesser of the lease term or estimated useful life for leasehold improvements. Intangible assets are being amortized using the straight-line method over their estimated useful lives of 15 years.

Interest expense

Interest expense includes the cash and non-cash interest cost for all debt instruments. Interest expense is recognized under the effective interest method such that non-cash interest includes the additional expense recognized over and above the cash interest paid during a period as a result of the application of the effective interest method.

Change in fair value of financial instruments

Change in fair value of financial instruments includes the change in the Amended Royalty Agreement (defined below) liability, the Warrant liability, the Derivative liability, and the Preferred stock conversion liability, which are marked to fair value on a quarterly basis.

Net loss

Net loss includes the results from revenue recognized during the period after deducting all operating and non-operating expenses.

Results of Operations

The following table summarizes our results of operations for the three months ended September 30, 2016 and 2015:

	Three Months Ended September 30,	
	2016	2015
	(in thousands, except per share data)	
Revenue	\$ 1,713	\$ 3,187
Operating expenses:		
Research and development	6,803	16,004
Selling, general and administrative	8,178	9,228
Depreciation and amortization	1,690	1,543
Total operating expenses	16,671	26,775
Operating loss	(14,958)	(23,588)
Interest expense	4,286	1,684
Change in fair value of financial instruments	(1,261)	602
Other income, net	(10)	(10)
Net loss	\$ (17,973)	\$ (25,864)
Net loss per share:		
Basic and diluted net loss per share	\$ (1.08)	\$ (2.08)

Three Months Ended September 30, 2016 Compared to Three Months Ended September 30, 2015

Revenue. Revenue for the three months ended September 30, 2016 decreased by \$1.5 million, or 46.3%, as compared to the three months ended September 30, 2015. During the three months ended September 30, 2016, we recognized approximately \$0.4 million of revenue related to substantive milestones that were completed during the period pursuant to customer agreements to provide customization and development services, clinical support services, collaborative research activities and testing support services. Also, during the three months ended September 30, 2016, we recognized \$1.2 million in revenue related to services rendered on a time and materials basis, proportional performance method, the completed method and/or straight line basis over the requisite service period pursuant to customer agreements to provide various customization and development services. Also, during the three months ended September 30, 2016, we recognized \$0.1 million of license revenue. During the three months ended September 30, 2015, we recognized approximately \$1.8 million of revenue related to substantive milestones that were completed during the period pursuant to customer agreements to provide customization and development services, clinical support services, collaborative research activities and testing support services. Also during the three months ended September 30, 2015, we recognized \$1.4 million in revenue related to services rendered on a time and materials basis, proportional performance method, and/or straight line basis over the requisite service period pursuant to customer agreements to provide various customization and development services. The decrease in revenue is primarily related to timing of achievement of milestones under customer programs. Our revenue is expected to continue to fluctuate on a quarter to quarter basis.

Research and development expenses . Research and development expenses for the three months ended September 30, 2016 decreased by \$9.2 million, or 57.5%, as compared to the three months ended September 30, 2015 primarily due to decreased employee costs of \$3.2 million, decreased tooling, prototype, and material costs of \$2.6 million, decreased third party contracting costs of \$1.5 million, decreased share-based compensation of \$1.0 million, decreased travel costs of \$0.3 million and decreased other costs of \$0.5 million. The decrease in research and development expenses during the current period is related to cost reduction initiatives implemented during September and October 2015.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2016 decreased by \$1.1 million, or 11.4%, as compared to the three months ended September 30, 2015 primarily due to decreased share-based compensation of \$1.6 million, decreased employee costs of \$0.6 million, and decreased other costs of \$1.0 million offset by increased accounting fees of \$0.9 million, increased legal costs of \$0.4 million, and the \$0.8 million non-cash charge relating to the sublease. The increased accounting fees and legal fees are primarily related to the Investigation.

Depreciation and amortization expense. Depreciation and amortization expense for the three months ended September 30, 2016 increased by \$0.1 million, or 9.5%, as compared to the three months ended September 30, 2015 primarily as a result of accelerated depreciation of fixed assets related to the Subleased Portion offset by a reduction of equipment due to the impairment charge we recorded in fiscal 2016.

Interest expense. Interest expense for the three months ended September 30, 2016 increased by \$2.6 million, or 154.5%, as compared to the three months ended September 30, 2015 primarily attributable to interest on the OrbiMed Financing (\$1.4 million) and the Convertible Note (\$0.5 million), and a decrease in capitalized interest (\$0.7 million).

Change in fair value of financial instruments. Change in fair value of financial instruments for the three months ended September 30, 2016 decreased by \$1.9 million as compared to the three months ended September 30, 2015. A decrease of \$0.4 million is related to the change in the fair value of the Royalty liability in connection with the OrbiMed Financing which is revalued each quarter. A decrease of \$1.5 million is due to the remeasurement of the warrant liability due to a decrease in the Company's share price.

Net loss and net loss per share. Net loss during the three months ended September 30, 2016 and 2015 was \$18.0 million and \$25.9 million, respectively. The decrease in net loss is primarily due to the decrease in operating expenses and change in fair value of instruments offset by a decrease in revenue and an increase in interest expense. Basic and diluted net loss per share was \$1.08 and \$2.08 on weighted average shares outstanding of 16,627,517 and 12,452,799, respectively. The increase in the weighted average shares outstanding was primarily due to conversions of preferred shares under the Preferred Stock Purchase Agreement.

Liquidity and Capital Resources

As of September 30, 2016, the Company's unaudited cash balance was approximately \$8.1 million, including \$2.1 million of restricted cash, and the book value of our debt was \$109.2 million. As of September 30, 2016, the Company also had a working capital deficit of \$8.8 million. Under the Company's debt facilities, the Company was required to have a cash and restricted cash balance of \$5.1 million at September 30, 2016 and a cash and restricted cash balance of \$5.0 million at October 31, 2016.

The Company incurred recurring losses from operations as well as negative cash flows from operating activities during fiscal year 2016, and the three months ended September 30, 2016, and anticipates incurring additional losses and negative cash flows until such time that it can generate sufficient revenue from the sale, customization, or exclusive use and licensing of its proprietary injectable drug delivery systems to pharmaceutical and biotechnology customers. These factors raise substantial doubt about the Company's ability to continue as a going concern. In order for the Company to continue operations for the next 12 months and to be able to discharge its liabilities and commitments in the normal course of business, the Company intends to take the steps delineated under "Fundraising Efforts" below to address its cash requirements, the success of which is largely beyond the Company's control, and the Company has otherwise taken the steps outlined in this "Liquidity and Capital Resources" section.

Amgen Inc.

On October 24, 2016, the Company Parties and the Counterparty entered into the October Counterparty Letter Agreement, pursuant to which the Company Parties agreed to issue to the Counterparty on October 24, 2016, in accordance with the terms and conditions of the Counterparty SPA and the October Counterparty Letter Agreement, the Accelerated Convertible Note in the initial principal amount of \$10.0 million plus a \$0.6 million financing fee (the "Financing Fee"), for an aggregate initial principal amount of \$10.6 million. In consideration for issuing the Accelerated Convertible Note, the Counterparty paid to the Company \$10.0 million on October 24, 2016.

Pursuant to the October Counterparty Letter Agreement, the remaining \$5.0 million of the 2017 Convertible Note will continue to be issuable in January 2017 by the Company Parties to the Counterparty in accordance with the terms and conditions of the Counterparty SPA. The Lender has the right to consent to the issuance of such \$5.0 million portion of the 2017 Convertible Note. There can be no assurance as to when or if the Counterparty will purchase all or any part of the remaining portion of the 2017 Convertible Note and/or the 2018 Convertible Note, or if the Lender will consent to the issuance of the remaining portion of the 2017 Convertible Note.

OrbiMed

On February 22, 2016, in connection with the formation of the strategic collaboration with the Counterparty, Unilife Medical Solutions, Inc., a subsidiary of the Company (the “Borrower”), entered into an Eighth Amendment (the “Eighth Amendment to the Credit Agreement”) to the Credit Agreement, dated March 12, 2014, by and between ROS Acquisition Offshore LP (the “Lender”), an affiliate of OrbiMed Advisors (“OrbiMed”), and the Borrower (the “Credit Agreement,” and, as amended the “Amended Credit Agreement” or the “OrbiMed Financing”). Pursuant to and subject to the terms of the Eighth Amendment to the Credit Agreement, the Lender agreed to: (i) defer all obligations of the Borrower to pay interest to the Lender for the period from January 1, 2016 through February 22, 2018 at the rate specified in the Amended Credit Agreement, which interest will be added to the outstanding principal amount of the loan on the last day of each interest period; (ii) enable the Counterparty to take a security interest in certain inventory and intellectual property assets related to a specific device licensed to the Counterparty; and (iii) remove the minimum cash receipts covenant for all future periods. In addition, on February 22, 2016, the Borrower entered into the Sixth Amendment to the Royalty Agreement (the “Royalty Agreement,”) with Royalty Opportunities S.A.R.L. (“ROS”). Pursuant to and subject to the terms of the Sixth Amendment to the Royalty Agreement, ROS agreed to waive any rights to royalty payments otherwise payable as a result of the License Fee and the proceeds of the Notes with the Counterparty, and to defer royalty payments payable on revenues received by the Company from the Counterparty until after the end of the first fiscal quarter in which the Company sells a commercial quantity of devices developed for the Counterparty. In connection with entering into the Eighth Amendment to the Credit Agreement and the Sixth Amendment to the Royalty Agreement, the Company issued to ROS a warrant to purchase, at any time until February 22, 2026, 1,673,981 shares of common stock, at an exercise price of \$12.50 per share, subject to adjustment for certain events. See note 10 “Long Term Debt” for accounting considerations relating to such warrant.

Cost Reduction Initiatives

During the three months ended September 30, 2016, we reduced our headcount by approximately 10 employees. Such headcount reductions are expected to reduce annual operating costs by approximately \$0.6 million. We do not believe that these cost reduction initiatives will negatively impact our ability to serve our customers.

In addition, the Company, on June 20, 2016, subleased a portion (the “Subleased Portion”) of its King of Prussia, Pennsylvania facility (the “Facility”). During the term of the sublease, which commenced on October 1, 2016 and will end on March 31, 2019, the Company will be entitled to receive an aggregate of approximately \$1.3 million in rent with respect to the Subleased Portion. During the same time period, the Company will be obligated under the Company’s lease agreement relating to the Facility to pay an aggregate of approximately \$1.9 million in rent with respect to the Subleased Portion. Assuming the sublessor exercises its renewal option, the Company will be entitled to receive approximately an additional \$1.9 million over the renewal term of April 1, 2019 through June 30, 2022 and the Company will be obligated under the Company’s lease agreement relating to the Facility to pay an aggregate of approximately \$2.5 million over the same time period. The Company ceased using the Subleased Portion as of July 20, 2016. During the three months ended September 30, 2016, the Company recorded a non-cash charge of \$1.3 million which consisted of two components: (i) \$0.7 million related to the discounted fair value of the difference between the amounts to be received from the sublessor and the amounts to be paid to the landlord, adjusted by costs previously deferred related to the Subleased Portion; and (ii) \$0.6 million related to accelerated depreciation of fixed assets related to the Subleased Portion.

Cash Receipts

The Company expects to generate cash receipts from wearable injector customers during fiscal 2017 and the Company continues to have business development discussions with current and prospective wearable injector customers. The Company is, however, unable to predict the amount, if any, or the timing of such receipts or any proceeds from these business development discussions.

Fundraising Efforts

The Company’s ability to raise capital will be limited and there can be no assurance that financing will be available when needed. The Company will not be able to obtain financing through offerings of its securities registered under the Securities Act, as amended, for the near future and until the Company can prepare, file with the SEC, and cause to become effective a registration statement on Form S-1. We are not currently eligible to register the offer and sale of our securities using a registration statement on Form S-3, cannot use our existing Form S-3 and will not become eligible to use Form S-3 until we have timely filed certain periodic reports required under the Exchange Act for 12 consecutive calendar months. As a result, the Company will not be able to obtain financing under the Controlled Equity Offering Sales Agreement that the Company entered into with Cantor Fitzgerald & Co. on July 29, 2015 (the “New Sales Agreement”) or the equity purchase agreement that the Company entered into with Lincoln Park Capital Fund, LLC (“LPC”) on July 29, 2015 (the “LPC Purchase Agreement”) at least until the Company is eligible to register the offer and sale of our securities using a registration statement on Form S-3.

Pursuant to the Counterparty SPA, the Counterparty may purchase up to an additional \$5.0 million in Notes in January 2017 (the “2017 Convertible Note”), and up to an additional \$10.0 million in Notes in January 2018 (the “2018 Convertible Note”). See note 9 “Long-Term Debt – Senior Secured Convertible Note” for more information regarding the Notes. There can be no assurance as to when or if the Counterparty will purchase all or any part of the remaining portion of the 2017 Convertible Note and/or the 2018 Convertible Note, or if the Lender will consent to the issuance of the remaining portion of the 2017 Convertible Note.

The Company has also engaged a financial advisory firm to further assist with fundraising efforts. There is no assurance that the financial advisory firm will be successful in these efforts.

The Company believes its existing cash at September 30, 2016 and the proceeds from the Accelerated Convertible Note received on October 24, 2016 will provide the Company with sufficient liquidity to meet its minimum cash balance requirement of \$5.3 million and fund the Company’s operations through January 2017. The Company believes that potential proceeds from business development discussions, the potential issuance of the remaining \$5.0 million portion of the 2017 Convertible Note and fundraising efforts along with potential customer cash receipts, will provide the Company with enough liquidity to fund its operations for the next twelve months. However, there can be no assurance that any cash from such business development discussions, potential issuance of the remaining \$5.0 million portion of the 2017 Convertible Note, fundraising efforts, or customer receipts will be available when needed, as such sources of liquidity largely are beyond the Company’s control. If we are unable to obtain financing when needed, we may be in default under one or more of our debt obligations unless we are able to obtain waivers from our lenders. A breach of any of the covenants related to our debt instruments could result in a higher rate of interest to be paid or the lenders could elect to declare all amounts outstanding under the applicable agreements to be immediately due and payable. If the lenders were to make such a demand for repayment, we would be unable to pay the obligations as we do not have existing facilities or sufficient cash on hand to satisfy these obligations. Under the circumstances, we also would be unable to pay our other obligations as they come due, which could prompt our creditors to pursue other remedies. These factors continue to raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The following table summarizes our cash flows during the three months ended September 30, 2016 and 2015:

	Three Months Ended September 30,	
	2016	2015
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (12,503)	\$ (13,623)
Investing activities	(363)	(2,785)
Financing activities	141	9,894

Net Cash Used In Operating Activities

Net cash used in operating activities during the three months ended September 30, 2016 was \$12.5 million compared to \$13.6 million during the three months ended September 30, 2015. The decrease in net cash used in operating activities was primarily due to a decrease in operating expenses, increase in deferred revenue and accounts payable; offset by a decrease in accrued expenses and increase in accounts receivable.

Net Cash Used in Investing Activities

Net cash used in investing activities during the three months ended September 30, 2016 and 2015 was \$0.4 million and \$2.8 million, respectively. The decrease in net cash used in investing activities is primarily due to our focus on wearable injector products which require less capital investment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the three months ended September 30, 2016 was \$0.1 million compared to \$9.9 million during the three months ended September 30, 2015.

During the three months ended September 30, 2016, we made \$0.1 million in principal debt repayments and royalty payments offset by a decrease in restricted cash of \$0.3 million.

During the three months ended September 30, 2015, we received \$9.3 million in net proceeds from the issuance of common stock from our New Sales Agreement with Cantor Fitzgerald & Co. and our Purchase Agreement with LPC, \$0.6 million in proceeds from borrowings from our former CEO, which was partially offset by \$0.4 million in principal debt repayments and royalty payments.

Contractual Obligations and Commitments

The following table provides information regarding our contractual obligations as of September 30, 2016:

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
	(In thousands)				
Long-term debt and related interest	\$ 186,273	\$ 1,528	\$ 17,651	\$ 105,975	\$ 61,119
Operating leases	7,368	1,244	2,522	2,604	998
Purchase obligations	229	229	—	—	—
Total contractual obligations	<u>\$ 193,870</u>	<u>\$ 3,001</u>	<u>\$ 20,173</u>	<u>\$ 108,579</u>	<u>\$ 62,117</u>

The table above does not reflect any cash inflows relating to the Subleased Portion.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk from changes in interest rates and foreign currency exchange rates. Changes in these factors could cause fluctuations in our results of operations and cash flows.

Interest Rate Risk

Our exposure to interest rate risk is limited to our cash and cash equivalents that are invested in money market funds with highly liquid short term investments and our variable interest rate term loans. We currently do not utilize derivative instruments to mitigate changes in interest rates.

Foreign Currency Exchange Rate Fluctuations

Certain of our revenues are derived from payments under our exclusive agreement received in euros while we incur most of our expenses in U.S. dollars and Australian dollars. In addition, a portion of our cash and cash equivalents and investments are held at Australian banking institutions and are denominated in Australian dollars. We are exposed to foreign currency exchange rate risks on these amounts. We currently do not utilize options or forward contracts to mitigate changes in foreign currency exchange rates. For U.S. reporting purposes, we translate all assets and liabilities of our non-U.S. entities into U.S. dollars using the exchange rate as of the end of the related period and we translate all revenues and expenses of our non-U.S. entities using the average exchange rate during the applicable period.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (“Exchange Act”)) are designed to provide reasonable assurance that information required to be disclosed in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

All internal control systems, no matter how well designed and tested, have inherent limitations, including, among other things, the possibility of human error, circumvention or disregard. Therefore, even those systems of internal control that have been determined to be effective can provide only reasonable assurance that the objectives of the control system are met and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As previously disclosed in the Company's 2016 10-K, the Company's current management discovered violations of Company policies and procedures and possible violations of laws and regulations by Alan Shortall, the Company's former Chief Executive Officer, and Jim Bosnjak, the Company's former Chairman and member of the Board of Directors ("Board"). Mr. Shortall's employment with the Company ceased on March 11, 2016, and Mr. Bosnjak resigned from the Board on August 24, 2015. The Board established a Special Committee to oversee an independent investigation. External counsel conducted the investigation with the assistance of an advisory firm with forensic accounting expertise (the "Investigation"). The Investigation did not identify any material financial loss to the Company.

The Company carried out an evaluation, of the effectiveness of the design and operation of its disclosure controls and procedures as of September 30, 2016. Due to the material weaknesses in internal control over financial reporting as described in "Management's Report on Internal Control over Financial Reporting" below, our CEO and CFO have concluded that our disclosure controls and procedures were not effective, and were not operating at a reasonable assurance level as of September 30, 2016.

Management's Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining effective internal control over financial reporting and for assessing the effectiveness of internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting refers to a process designed by, or under the supervision of, our Chief Executive Officer and our Chief Financial Officer and effected by our Board, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and members of our Board; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements.

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

A material weakness (as defined in Rule 12b-2 under the Exchange Act) is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis.

Management, under the supervision of the Company's CEO and CFO, and oversight of the Board, conducted an assessment of the effectiveness of internal control over financial reporting. Management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission's 2013 Framework (the "COSO 2013 Framework"). Management has determined the following material weaknesses existed at September 30, 2016:

The Company, under the oversight of the Board and the leadership of Mr. Shortall, did not have an effective control environment, risk assessment process, information and communication process and monitoring activities; specifically:

- The Company failed to establish a tone at the top that demonstrated its commitment to integrity and ethical values. Mr. Shortall created instances where certain personnel participated in override of the Company's policies and procedures and internal controls without exercising the appropriate professional skepticism and failed to communicate the override of controls to others.
- The Company did not have an effective annual process in place to ensure that all employees, including management, confirmed their compliance with the Company's Business Conduct Policy and that deviations from the expected standards of conduct were identified and remedied in a timely manner.
- The Company did not have a sufficient number of trained resources with assigned responsibility and accountability for financial reporting processes and the design, documentation and effective operation of internal controls to effectively adopt the COSO 2013 Framework.

- The Company did not have an effective, documented and continuous risk assessment process to identify and analyze risks of financial misstatement due to error and/or fraud, including management override of controls, and determine an appropriate action to manage the financial reporting risks.
- The Company did not have effective information and communication and monitoring controls to ensure the timely identification and communication of related party transactions to financial reporting personnel, management, and the Board, to enable appropriate financial reporting and disclosure of such transactions.

As a consequence of the inappropriate tone at the top and the above-mentioned entity level deficiencies, the following process level control deficiencies were identified:

- Ineffective operation of certain process level controls due to management override of controls resulting from the dominant influence of the former CEO, including ineffective process-level controls over the accounting for related party transactions and the evaluation of transactions with senior executives and a former Board member that represented loans and advances. In addition, the Company did not involve those employees with the appropriate knowledge and expertise to evaluate the business purpose of the transactions and compliance with laws and regulations.
- Ineffective design and implementation and documentation of management review controls, specifically, the management review controls did not adequately address or document management's expectations, criteria for investigation, the level of precision used in the performance of the review control, and how outliers were identified, investigated and resolved.
- Ineffective general information technology controls (GITCs) for the significant IT platforms due to inadequate IT resources. Specifically, the Company did not have effectively designed and documented program change controls and effective user access controls over IT operating systems, databases and IT applications. Accordingly, process level automated controls and compensating manual controls that were dependent upon the information derived from the IT systems were determined to be ineffective.

These control deficiencies create a reasonable possibility that a material misstatement to the consolidated financial statements will not be prevented or detected on a timely basis. Accordingly, we concluded that the control deficiencies represent material weaknesses in the Company's internal control over financial reporting and our internal control over financial reporting was not effective as of September 30, 2016.

Remediation of Material Weaknesses

The Company continues to work, to strengthen our internal control over financial reporting. We are committed to ensuring that such controls are designed and operating effectively. Our Board and management take internal controls over financial reporting and the integrity of the Company's financial statements seriously and believe that the remediation steps described below, including with respect to personnel changes, were and are essential steps to establishing and maintaining strong and effective internal controls over financial reporting and addressing the tone at the top concerns that contributed to the material weaknesses identified. The following actions and plans will be or have been implemented:

- The Board replaced Mr. Shortall effective March 2016 with our then interim and now current CEO, John Ryan, effective March 2016. Mr. Bosnjak resigned in August 2015. Mary Kate Wold, President and CEO of the Church Pension Group, a former finance executive at Wyeth and previously the Company's Vice Chair and Lead Independent Director, assumed the role of Board Chair. In addition, the Controller is no longer serving as Chief Accounting Officer, Controller or Treasurer. The Company appointed David Hastings as the Company's Chief Accounting Officer and Treasurer along with Mr. Hastings' current role as Chief Financial Officer. The Company also appointed three new independent Board members.
- Management has evaluated and revised the assignment of authorities and financial reporting responsibilities and roles and has made staffing changes including, without limitation, those noted above; and the Company will increase technical training to those employees involved in the financial reporting process.
- The Company has increased communication and will increase training to employees and the Board regarding the ethical values of the Company and the requirement to comply with laws, rules, regulations, and Company policies, including the Business Conduct Policy and Insider Trading Policy, and the importance of accurate and transparent financial reporting. In addition, the Company will revise its process to ensure that all employees annually confirm compliance with the Company's Business Conduct Policy and that deviations are identified and timely remediated.
- The Company will implement a regularly recurring risk assessment process focused on identifying and analyzing risks of financial misstatement due to error and/or fraud, including management override of controls.

- Under the supervision of the Board, the Company will emphasize to key leadership the importance of setting appropriate tone at the top and of appropriate behavior with respect to accurate financial reporting and adherence to the Company's internal control over financial reporting framework and accounting policies.
- The Board will work with the Company to implement an internal audit function and develop a risk based plan that will monitor the Company's adherence to its policies and procedures including, without limitation, those policies and procedures related to the identification and disclosure of related party transactions, and to review any areas of concern or emphasis that the Board has identified as part of its oversight.
- The Company will update its policies and procedures to require the identification of related party transactions, transactions with senior executives, and to enhance the review and approval for these types of transactions and ensure their disclosure; and will train all employees on such updated policies.
- Management review controls will be reassessed to determine the appropriate level of precision required to mitigate the potential for a material misstatement. In addition, the Company will enhance its design and implementation and supporting documentation over management review controls to make clear: (i) management's expectations related to transactions that are subject to such controls; (ii) the level of precision and criteria used for investigation; and (iii) evidence that all outliers or exceptions that should have been identified are investigated.
- The Company will design and document its general information technology controls specifically, program change controls, user access controls designed to restrict IT and financial users' access and monitoring controls designed to actively monitor program changes and user access activities.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the first quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

As noted above, the Company began the process of enhancing existing controls and designing and implementing additional controls and procedures in response to the material weaknesses.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, the Company is involved in various legal proceedings, claims, suits and complaints arising out of the normal course of business. Based on the facts currently available to the Company, management believes that these claims, suits and complaints are adequately provided for, covered by insurance, without merit or that it is not probable that an unfavorable outcome will result.

In addition, the Company is or was involved in the following legal proceedings. A former employee, Talbot Smith, who was terminated for cause by Unilife, filed a civil complaint in the United States District Court of the Eastern District of Pennsylvania on August 30, 2013, and an amended complaint on March 5, 2014, alleging that he was wrongly terminated in retaliation for making allegations about the Company's compliance practices. Following the discovery process, Mr. Smith dismissed his claims against the Company with prejudice. In connection with the resolution and dismissal of the action, Mr. Smith agreed to make a payment to the Company to settle counter claims the Company had brought against him. Mr. Smith received no payment as part of the resolution and dismissal of his claims against the Company, his attorney received a reduced portion of her fees from the Company's insurer, and the matter is now concluded.

As previously disclosed, subsequent to the filing of an OSHA complaint by Mr. Smith, we received a subpoena from the staff of the SEC (the "Staff") requesting the Company to provide certain information to the Staff, which is generally consistent with the meritless allegations made by Mr. Smith in his OSHA complaint. In his complaint filed in the United States District Court for the Eastern District of Pennsylvania, Mr. Smith stated that he provided the Staff with information about his allegations in July and August 2012. The Company responded to that subpoena and has received additional subpoenas and requests for information from the Staff, requesting additional information consistent with the first subpoena. The Staff has also requested information about public statements made by the Company's former Chief Executive Officer. The Company has provided the requested information to the Staff.

On May 8, 2016, the Company announced an investigation into violations of the Company's policies and procedures and possible violations of laws and regulations by the Company's former Chief Executive Officer, Alan Shortall, whose employment with the Company ceased on March 11, 2016, and its former Chairman, Jim Bosnjak, who resigned from the Board on August 24, 2015 (the "Investigation"). The Investigation was completed on October 7, 2016, and the Company has reported to the SEC on the Company's findings from the Investigation, has responded to questions from the Staff regarding the findings, and is cooperating fully with the Staff. To date, the SEC has not indicated whether any fines or penalties will be assessed against the Company in relation to these matters. The Company is unable to predict what action the SEC or other regulatory authority may take, if any, in relation to these matters or the impact, if any, of any such action on the Company's business, operations, cash flows and/or financial condition. If any fines or penalties are assessed against the Company they may be material.

As previously disclosed, on January 8, 2014, the Company was served with a derivative complaint filed in the Delaware Chancery Court (the "Court") by Cambridge Retirement System ("Cambridge"), a purported stockholder of the Company, against its then-current Board of Directors to recover allegedly "excessive and wasteful" compensation paid to the non-executive directors since 2010. In June, 2014, pursuant to the Company's motion to dismiss the complaint, the Court dismissed Cambridge's complaint with respect to the directors' equity grants, but denied the motion with respect to their cash compensation. The Company filed an answer to the remaining claims in July 2014 and, in June 2015, the Company and Cambridge entered into a Memorandum of Understanding ("MOU") agreeing to the basic terms of a non-monetary settlement of the action.

On March 18, 2016, Cambridge agreed to voluntarily dismiss its derivative complaint. No compensation in any form was provided to either Cambridge or its counsel in exchange for its agreement to voluntarily dismiss the lawsuit. Because Cambridge agreed to voluntarily dismiss the lawsuit, the MOU has become null and void and of no further legal effect. On March 18, 2016, the Court entered a stipulated order regarding notice of the proposed dismissal of all claims in the derivative action (the "Proposed Dismissal Order"). On April 18, 2016, the Court entered that stipulation as an order, dismissing the case with prejudice.

On September 14, 2015, UMSI was served with a complaint filed in the Superior Court of the State of Connecticut by Bidel, Inc. ("Bidel") seeking (1) to temporarily enjoin UMSI from entering into a transaction that would jeopardize the Company's ability to perform its obligations under the Customization and Commercial Supply Agreement effective April 8, 2013 (as amended, the "First Bidel Agreement") between Bidel and UMSI; and (2) damages under the Connecticut Unfair Trade Practices Act. Bidel alleged that UMSI had engaged in unfair and deceptive trade practices by purportedly misrepresenting its ability and willingness to satisfy its obligations under the First Bidel Agreement and requesting additional payments from Bidel to satisfy the Company's obligations. Additionally, Bidel filed a demand for arbitration with the American Arbitration Association (AAA) asserting that UMSI had breached its obligations relating to the timing and scope of its performance under the First Bidel Agreement. The Company filed counterclaims in the arbitration for commercial disparagement and breach of the confidentiality provisions of the agreement.

On September 2, 2016, Bidel, the Company and UMSI entered into an Asset Purchase and License Agreement (the “Second Bidel Agreement”) which provides: (a) for the termination of the First Bidel Agreement; (b) for the grant of an exclusive license for a six-month term to the intellectual property rights related to the Unilife mixing device; (c) a six-month term during which Bidel can exercise an option (the “Option”) to purchase certain assets associated with the First Bidel Agreement for \$1.5 million (the “Potential Asset Sale”) and extend Bidel’s license, for fees based on intellectual prosecution and maintenance costs determined on an annual basis; (c) dismissal, with prejudice, of all active proceedings in connection with the litigation and arbitration proceedings pending between Bidel and UMSI. Under the Second Bidel Agreement, each party also releases the other party of all liability, waives all claims with prejudice, and forever holds the other party harmless from any damages arising out of relating to the First Bidel Agreement. Bidel and UMSI each paid their respective attorneys’ fees and UMSI paid no monetary amount to Bidel in connection with this resolution.

On March 24, 2016, Edward Fine filed a complaint against the Company and Unilife Medical Solutions Limited (“UMSL”) in the Superior Court of New Jersey. The complaint alleges that the Company and UMSL are in breach of contract and have been unjustly enriched as a result of UMSL’s failure to pay certain required payments under a consultancy agreement between Mr. Fine and UMSL. Pursuant to the complaint, Mr. Fine is seeking monetary damages in the amount of \$288,000 in the aggregate. The Company believes that Mr. Fine’s claims and demands for relief are wholly without merit and the Company is vigorously defending the action. On August 15, 2016, we filed an Answer, Affirmative Defenses and Counterclaims, wherein we asserted counterclaims against Mr. Fine for fraud, civil conspiracy, unjust enrichment, breach of contract, and breach of the implied covenant of good faith and fair dealing arising out of Mr. Fine’s role in certain previously disclosed transactions involving Mr. Fine and Jim Bosnjak, the Company’s former Chairman of the Board. For additional information regarding such transactions, see the Company’s Current Report on Form 8-K filed with the SEC on July 28, 2016 under the heading the “Bosnjak Loan Payments and Unrepaid Personal Expenses.” This action is currently in a 450-day discovery period which commenced on July 29, 2016.

On May 26 and 27, 2016, two putative class actions were filed in the United States District Court for the Southern District of New York alleging that in violation of Rule 10b-5 and Section 20(a) of the Exchange Act, the Company and six individual defendants made false and/or misleading statements and/or failed to disclose: (1) that the Company’s former CEO and former Chairman of the Board of Directors had violated the Company’s policies and procedures and had engaged in violations of law and regulations; (2) that the Company lacked adequate internal controls over accounting and financial reporting; (3) that, as a result, the Company would be unable to file its Quarterly Report on Form 10-Q for the period ended March 31, 2016 by the prescribed filing deadline; and (4) that, as a result of the foregoing, the Company’s financial statements, as well as its statements about the Company’s business, operations, and prospects, were false and misleading and/or lacked a reasonable basis. The putative class actions were brought on behalf of purchasers of the Company’s securities between February 3, 2014 and May 23, 2016. On August 24, 2016, the Court consolidated the two actions, appointed lead plaintiffs and lead counsel, and set a deadline of October 24, 2016 for Plaintiffs to file an amended complaint. The plaintiffs filed an amended complaint on October 24, 2016 expanding the class to purchasers of the Company’s securities between November 9, 2011 and July 28, 2016, dropping three of the original individual defendants as named defendants and making additional allegations related to matters the Company disclosed in connection with the Investigation. The Company intends to vigorously contest this lawsuit.

On July 11, July 28, and August 1, 2016, respectively, derivative complaints were filed in the Court of Common Pleas in York County, Pennsylvania against 11 current or former directors and/or officers, alleging (i) breach of their fiduciary duties, (ii) unjust enrichment, (iii) abuse of control, (iv) gross mismanagement, and (v) corporate waste. The complaints allege, among other things, that the individual defendants breached the fiduciary duties they owed to the Company by (1) grossly mismanaging the Company and perpetuating a variety of self-serving schemes to benefit themselves and other interested parties and (2) making and/or causing the Company to make false/misleading statements or omissions of fact in its public disclosures. The complaints further allege that as a result of this alleged conduct, the Company will lose and expend millions of dollars. The Company intends to vigorously contest these lawsuits.

On August 17, 2016, Kahle Automation, S.r.l. (“Kahle”) filed a complaint against Unilife Medical Solutions, Inc. (“UMS”) in the United States District Court for the District of New Jersey. The complaint alleges that UMS breached contracts with Kahle for Kahle’s supply of automation systems for UMS Nexus and Finesse product lines. Kahle seeks monetary damages of \$4.2 million which includes alleged damages that we believe are not recoverable, such as \$0.9 million for bank fees, and \$0.8 million for lost profits. Kahle also seeks injunctive relief enjoining UMS from using the Nexus System and requiring UMS to take delivery of work in process related to the Finesse System. UMS disputes Kahle’s allegations that UMS terminated its agreement with Kahle for the Finesse System. We intend to defend ourselves vigorously against these claims.

The Company believes that depending on the outcome, certain of these matters may have a material impact to the Company or its business. See Part I, Item 1A Risk Factors – “Matters relating to or arising from the Investigation, including regulatory proceedings, litigation and potential additional expenses, may adversely affect our business and results of operations” of the 2016 10-K.

Item 6. Exhibits

The exhibits to this report are listed in the Exhibit Index below.

Exhibit No.	Description of Exhibit	Included Herewith
10.1	Letter Agreement, dated July 28, 2016, between Unilife Corporation, Unilife Medical Solutions, Inc. and Amgen Inc.	X
10.2	Letter Agreement, dated July 28, 2016, between Unilife Corporation, Unilife Medical Solutions, Inc. and Amgen Inc.	X
10.3+	Employment Agreement, dated July 28, 2016, by and between Unilife Corporation and John C. Ryan is incorporated by reference to Exhibit 10.1 of Unilife Corporation's Current Report on Form 8-K filed July 28, 2016	
10.4	Letter Agreement, dated September 29, 2016, between Unilife Corporation, Unilife Medical Solutions, Inc. and Amgen Inc. is incorporated by reference to Exhibit 10.55 of Unilife Corporation's Annual Report on Form 10-K filed October 24, 2016	
10.5	Letter Agreement, dated September 30, 2016, between Unilife Medical Solutions, Inc. and ROS Acquisition Offshore LP is incorporated by reference to Exhibit 10.56 of Unilife Corporation's Annual Report on Form 10-K filed October 24, 2016	
31.1	Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer	X
31.2	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer	X
32.1	Section 1350 Certification of the Chief Executive Officer	X
32.2	Section 1350 Certification of the Chief Financial Officer	X
101.INS**	XBRL Instance Document	X
101.SCH**	XBRL Taxonomy Extension Schema	X
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase	X
101.LAB**	XBRL Taxonomy Extension Label Linkbase	X
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase	X
101.DEF**	XBRL Taxonomy Extension Definition Linkbase	X

+ Indicates a management contract or compensatory plan.

** Attached as Exhibits 101 are the following financial statements from Unilife Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Unaudited Consolidated Balance Sheets as of September 30, 2016 and June 30, 2016, (ii) Unaudited Consolidated Statement of Operations and Comprehensive Loss for the three months ended September 30, 2016 and 2015, (iii) Unaudited Consolidated Statement of Stockholders' Deficit for the three months ended September 30, 2016, (iv) Unaudited Consolidated Statements of Cash Flows for the three months ended September 30, 2016 and 2015, and (v) Notes to Unaudited Consolidated Financial Statements.

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.

Date: November 14, 2016

UNILIFE CORPORATION

By: /s/ David C. Hastings
David C. Hastings
Chief Financial Officer
(Duly Authorized Officer and Principal Financial Officer)

AMGEN

Amgen
One Amgen Center Drive
M/S 28-5-C
Thousand Oaks, CA 91320-1799
805.447.1000
Fax: 805.499.6751

July 28, 2016

Unilife Corporation
250 Cross Farm Lane
York, PA 17406
Attention: John C. Ryan
Facsimile No.: (717) 384-3402

Re: Convertible Notes Due 2023

Dear John:

Reference is made to the Securities Purchase Agreement dated February 22, 2016 (the "Purchase Agreement") among Unilife Corporation ("Holdings"), Unilife Medical Solutions, Inc. and Amgen Inc. ("Amgen"), and to the 6% Senior Secured Convertible Note Due 2023 dated February 22, 2016 issued to Amgen, and the subsequent such notes that may be purchased by Amgen in 2017 and 2018 pursuant to the Purchase Agreement (collectively, the "Notes").

Whereas each of Holdings, Unilife Medical Solutions, Inc. and Amgen desires to limit the right of Amgen to convert the Notes into common stock of Holdings, and notwithstanding Amgen's rights under the Notes to convert the Notes into common stock of Holdings, Amgen agrees hereby that it shall not convert the Notes into common stock of Holdings if, but solely to the extent, such conversion would cause Amgen to beneficially own 10% or more of the outstanding common stock of Holdings immediately following such conversion (the "Conversion Limit").

Amgen shall have the unilateral right, in its sole discretion, to terminate the Conversion Limit at any time by providing written notice of such termination in accordance with the notice provisions of the Purchase Agreement (Section 10.3 thereof) to Holdings at least seventy-five (75) days prior to the date Amgen will terminate the Conversion Limit. Except as explicitly set forth herein, nothing in this letter is intended to limit, restrict or otherwise modify Amgen's right to convert the Notes into common stock of Holdings, or to purchase or sell common stock of Holdings.

Please sign this letter below to confirm your agreement with the foregoing.

Sincerely,

Amgen, Inc.

By: /s/ David Piacquad

Name: David Piacquad

Title: Sr. Vice President,
Business Development

Acknowledged and Agreed:

Unilife Corporation

By: /s/ John Ryan

Name: John Ryan

Title: Interim President and Chief Executive Officer,
Senior Vice President, General Counsel and
Secretary

Unilife Medical Solutions, Inc.

By: /s/ David Hastings

Name: David Hastings

Title: Senior Vice President and
Chief Financial Officer

Amgen Contract No.: 2016653390-001



July 28, 2016

BY FACSIMILE AND FEDEX

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
Attention: Corporate Secretary (Fax: (805) 447-1010)

Re: Waiver of Rights Under SPA and Promissory Note

Ladies and Gentlemen:

Reference is made herein to that certain (i) Securities Purchase Agreement (the "SPA"), dated as of February 22, 2016, by and among Unilife Corporation ("Unilife"), Unilife Medical Solutions, Inc. ("UMS") and Amgen Inc. ("Amgen"); and (ii) 6% Senior Secured Convertible Note Due 2023, dated as of February 22, 2016, issued by Unilife and UMS to Amgen in the aggregate principal amount of U.S. \$30,000,000 (the "2016 Note"). Capitalized terms used herein but otherwise not defined shall have the meanings ascribed to such terms in the SPA.

As you are aware, Unilife failed to timely file with the U.S. Securities and Exchange Commission (the "Commission") its Quarterly Report on Form 10-Q for the quarter ended March 30, 2016 (the "Form 10-Q"), which was due to be filed with the Commission on May 10, 2016. Unilife is currently in the process of preparing the Form 10-Q for filing with the Commission and, as noted in Unilife's Current Report on Form 8-K filed with the Commission on July 17, 2016, the Company intends to file the Form 10-Q with the Commission on or prior to November 7, 2016 (the "Filing Deadline Date").

Pursuant to Section 6.3(i) of the SPA, until the date on which Amgen shall have sold all the Conversion Shares and none of the Notes are outstanding, Unilife is required to timely file all reports required to be filed with the Commission pursuant to the Exchange Act or the rules and regulations thereunder. In addition, pursuant to Section 4(a)(viii) of the 2016 Note, an "Event of Default" (as defined in the 2016 Note) will have occurred in the event that Unilife materially breaches any covenant or other term or condition in the SPA and such material breach continues for a period of at least ten (10) consecutive Business Days (as defined in the 2016 Note) after written notice thereof is received by Unilife from Amgen.

Unilife Corporation

250 Cross Farm Lane, York, PA 17406 T + 1 717 384 3400 F + 717 384 3401 E info@unilife.com W www.unilife.com

By countersigning this letter agreement, (i) until 11:59 p.m. New York City time on the Filing Deadline Date, Amgen waives any and all rights what soever that Amgen has or may have under the Transaction Documents to declare an “Event of Default” under the 2016 Note as a result of Unilife’s failure to timely file the Form 10-Q with the Commission; and (ii) Amgen acknowledges and agrees that the filing by Unilife of the Form 10-Q with the Commission shall cure any breach of Section 6.3(i) of the SPA as a result of Unilife’s failure to timely file the Form 10-Q with the Commission.

Very yours truly,

UNILIFE CORPORATION

By: /s/ John Ryan
Name: John Ryan
Title: Interim President and Chief Executive Officer,
Senior Vice President, General Counsel and
Secretary

UNILIFE MEDICAL SOLUTIONS

By: /s/ David Hastings
Name: David Hastings
Title: Senior Vice President and Chief Financial Officer

CONFIRMED AND AGREED TO:

AMGEN INC.

By: /s/ Bethany Mancilla
Name: Bethany Mancilla
Title: Vice President,
Business Development

**Certification of Chief Executive Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, John Ryan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Unilife Corporation;
 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
-

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

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

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

/s/ John Ryan

Name: John Ryan

Title: Chief Executive Officer

Date: November 14, 2016

**Certification of Chief Financial Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, David C. Hastings, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Unilife Corporation;
 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
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5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

/s/ David C. Hastings

Name: David C. Hastings

Title: Chief Financial Officer

Date: November 14, 2016

**Certification of Chief Executive Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report on Form 10-Q of Unilife Corporation (the “Company”) for the quarterly period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, John Ryan, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ John Ryan

Name: John Ryan

Title: Chief Executive Officer

Date: November 14, 2016

**Certification of Chief Financial Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report on Form 10-Q of Unilife Corporation (the “Company”) for the quarterly period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, David C. Hastings, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ David C. Hastings

Name: David C. Hastings

Title: Chief Financial Officer

Date: November 14, 2016