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

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended March 31, 2015

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

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**UNILIFE CORPORATION**

(Exact name of registrant as specified in its charter)

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**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)

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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 May 8, 2015, 131,215,063 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)

	March 31, 2015	June 30, 2014
	(in thousands, except share data)	
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 37,116	\$ 8,368
Restricted cash	2,092	2,400
Accounts receivable	5,881	1,860
Inventories	137	142
Prepaid expenses and other current assets	968	1,108
Total current assets	46,194	13,878
Property, plant and equipment, net	62,031	54,588
Goodwill	9,726	11,830
Other assets	1,301	1,472
Total assets	<u>\$ 119,252</u>	<u>\$ 81,768</u>
<b>Liabilities and Stockholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 4,397	\$ 3,583
Accrued expenses	5,759	3,339
Current portion of long-term debt	904	613
Deferred revenue	5,778	717
Total current liabilities	16,838	8,252
Long-term debt, less current portion	79,136	54,835
Deferred revenue	19,050	12,550
Total liabilities	<u>115,024</u>	<u>75,637</u>
Contingencies (Note 10)		
Stockholders' Equity:		
Preferred stock, \$0.01 par value, 50,000,000 shares authorized as of March 31, 2015; none issued or outstanding as of March 31, 2015 and June 30, 2014	—	—
Common stock, \$0.01 par value, 250,000,000 shares authorized as of March 31, 2015; 131,293,733 and 103,617,278 shares issued, and 131,265,063 and 103,588,608 shares outstanding as of March 31, 2015 and June 30, 2014, respectively	1,313	1,036
Additional paid-in-capital	360,831	296,169
Accumulated deficit	(358,485)	(293,731)
Accumulated other comprehensive income	709	2,797
Treasury stock, at cost, 28,670 shares as of March 31, 2015 and June 30, 2014, respectively	(140)	(140)
Total stockholders' equity	<u>4,228</u>	<u>6,131</u>
Total liabilities and stockholders' equity	<u>\$ 119,252</u>	<u>\$ 81,768</u>

See accompanying notes to the consolidated financial statements.

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

	<b>Three Months Ended March 31,</b>		<b>Nine Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
	<b>(in thousands, except per share data)</b>			
Revenue	\$ 2,921	\$ 1,383	\$ 9,704	\$ 8,143
Research and development	13,213	8,018	35,498	22,224
Selling, general and administrative	9,055	6,649	26,763	19,872
Depreciation and amortization	1,184	1,026	3,537	3,068
Total operating expenses	23,452	15,693	65,798	45,164
Operating loss	(20,531)	(14,310)	(56,094)	(37,021)
Interest expense	1,796	809	4,710	5,640
Change in fair value of financial instruments	783	—	3,953	—
Other income, net	(5)	(10)	(3)	(25)
Net loss	(23,105)	(15,109)	(64,754)	(42,636)
Other comprehensive loss, net:				
Foreign currency translation	546	(429)	2,088	(147)
Comprehensive loss	<u>\$(23,651)</u>	<u>\$(14,680)</u>	<u>\$(66,842)</u>	<u>\$(42,489)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (0.20)</u>	<u>\$ (0.15)</u>	<u>\$ (0.59)</u>	<u>\$ (0.44)</u>

See accompanying notes to the consolidated financial statements.

**UNILIFE CORPORATION AND SUBSIDIARIES**  
**Consolidated Statement of Stockholders' Equity**  
**For the Nine Months Ended March 31, 2015**  
**(unaudited)**

	<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Accumulated</u>	<u>Treasury</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-In</u>	<u>Deficit</u>	<u>Other</u>	<u>Stock</u>	
			<u>Capital</u>		<u>Comprehensive</u>		
					<u>Income</u>		
			(In thousands, except share data)				
<b>Balance as of July 1, 2014</b>	103,617,278	\$1,036	\$296,169	\$ (293,731)	\$ 2,797	\$ (140)	\$ 6,131
Net loss	—	—	—	(64,754)	—	—	(64,754)
Foreign currency translation	—	—	—	—	(2,088)	—	(2,088)
Share-based compensation expense	9,217,655	92	7,713	—	—	—	7,805
Issuance of common stock from public offerings, net of issuance costs	18,458,800	185	56,949	—	—	—	57,134
<b>Balance as of March 31, 2015</b>	<u>131,293,733</u>	<u>\$1,313</u>	<u>\$360,831</u>	<u>\$ (358,485)</u>	<u>\$ 709</u>	<u>\$ (140)</u>	<u>\$ 4,228</u>

See accompanying notes to the consolidated financial statements.

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

	Nine Months Ended March 31,	
	2015	2014
	(in thousands)	
<b>Cash flows from operating activities:</b>		
Net loss	\$(64,754)	\$(42,636)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,537	3,068
Share-based compensation expense	7,805	6,875
Recognition of deferred revenue	(125)	(3,187)
Non-cash interest expense	1,339	3,610
Change in fair value of financial instruments	3,953	—
Changes in assets and liabilities:		
Accounts receivable	203	137
Inventories	5	8
Prepaid expenses and other current assets	140	(268)
Other assets	87	(355)
Accounts payable	843	781
Accrued expenses	3,259	1,485
Deferred revenue	7,462	17,500
<b>Net cash used in operating activities</b>	<b>(36,246)</b>	<b>(12,982)</b>
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(11,547)	(3,377)
<b>Net cash used in investing activities</b>	<b>(11,547)</b>	<b>(3,377)</b>
<b>Cash flows from financing activities:</b>		
Principal payments on long-term debt and capital lease obligations	(464)	(11,061)
Payment of royalty liability	(403)	—
Proceeds from issuance of long-term debt	20,000	40,000
Proceeds from the issuance of common stock, net of issuance costs	57,134	16,856
Proceeds from the exercise of options to purchase common stock	—	2,534
Payment of financing costs	(52)	(487)
Decrease in restricted cash	308	392
<b>Net cash provided by financing activities</b>	<b>76,523</b>	<b>48,234</b>
Effect of exchange rate changes on cash	18	108
<b>Net increase in cash and cash equivalents</b>	<b>28,748</b>	<b>31,983</b>
Cash and cash equivalents at beginning of period	8,368	5,736
Cash and cash equivalents at end of period	<u>\$ 37,116</u>	<u>\$ 37,719</u>
<b>Supplemental disclosure of non-cash activities</b>		
Purchases of property, plant and equipment in accounts payable and accrued expenses	<u>\$ 125</u>	<u>\$ 893</u>

See accompanying notes to the consolidated financial statements.

Unilife Corporation and Subsidiaries  
Notes to Unaudited Consolidated Financial Statements

## 1. Description of Business and Unaudited Financial Statements

Unilife Corporation and subsidiaries (the “Company”) is a U.S. based designer, manufacturer and supplier of innovative injectable drug delivery systems that can enhance and differentiate the injectable drugs, biologics and vaccines, or collectively injectable therapies, of its pharmaceutical and biotechnology customers. The Company has a broad portfolio of proprietary product platforms, including pre-filled syringes, drug reconstitution delivery systems, auto-injectors, wearable injectors, ocular delivery systems and other novel injectable drug delivery systems. Products within each platform are differentiated from competitors’ products with a series of innovative features designed to optimize the safe, simple and convenient administration of an injectable therapy. The Company sells its products directly to pharmaceutical and biotechnology companies who incorporate them into the drug-device combination product that is supplied pre-filled and ready for administration by end-users such as health-care providers or patients. Products within each of the Company’s platforms can be customized to address specific customer, therapy, patient and/or commercial requirements.

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, 2014 contained in its Annual Report on Form 10-K.

References to A\$ mean the lawful currency of the Commonwealth of Australia. References to € or euros are to the lawful currency of the European Union.

## 2. Liquidity

The Company has continued to incur recurring losses from operations during the fiscal year ended June 30, 2014, and the nine months ended March 31, 2015, and anticipates incurring additional losses until such time that it can generate sufficient revenue from the sale, customization, or exclusive use and licensing of its proprietary range of injectable drug delivery systems to pharmaceutical and biotechnology customers. Management has taken such steps delineated below to address its cash requirements.

In February 2015, the Company issued 12,650,000 shares of common stock and raised \$44.7 million, net of issuance costs, through an underwritten registered public offering. The Company intends to use the proceeds from the public offering for investments in its plant, equipment, systems and personnel to further develop its manufacturing and operational capabilities to satisfy current and future customer orders and for working capital and other general corporate purposes.

On March 12, 2014 (the “Closing Date”), Unilife Medical Solutions, Inc. (the “Borrower”), a wholly owned subsidiary of the Company, entered into a credit agreement (the “Credit Agreement”) with ROS Acquisition Offshore LP (together with its affiliates, successors, transferees and assignees, the “Lender” or ROS), an affiliate of OrbiMed Advisors. 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. A first tranche loan of \$40.0 million was drawn on the Closing Date and a further two tranches each of \$10.0 million (collectively, the “Loans”) were committed by the Lender. On September 30, 2014 the Borrower entered into a First Amendment to the Credit Agreement (“Amended Credit Agreement”) 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. Under the Amended Credit Agreement, Borrower’s prepayments and repayments of any unpaid principal amount of the Loans shall include a 10.0% repayment premium (with certain enumerated exceptions). The Amended Credit Agreement contains customary representations and warranties in favor of the Lender. The Amended Credit Agreement also contains certain covenants relating to financial performance and liquidity targets, among others.

Concurrent with the First Amendment to the Credit Agreement, the Borrower entered into the First Amendment to the Royalty Agreement (“Amended Royalty Agreement”). Pursuant to and subject to the terms of the Amended Royalty Agreement, Borrower has agreed to pay the Lender 3.875% on the first \$50.0 million of net sales in each fiscal year, plus 1.500% of net sales in excess of \$50.0 million and up to and including \$100.0 million in each fiscal year, plus 0.375% of net sales in excess of \$100.0 million in each fiscal year. Borrower has the right to buy out the Amended Royalty Agreement at any time on or before March 12, 2018 at a reduced amount. The buy-out amount ranges from \$9.75 million to \$26.25 million (such amount to be determined based on when the buy-out option is exercised), less amounts previously paid by Borrower to Lender pursuant to the Amended Royalty Agreement.



In October 2012, the Company entered into a Controlled Equity Offering Sales Agreement, (the “Sales Agreement”) 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 \$45.0 million. During the nine months ended March 31, 2015, the Company issued 5,808,800 shares of common stock and raised approximately \$12.4 million under the Sales Agreement, which was the full remaining amount available for sale under the Sales Agreement. As a result, the Company has completed use of the facility available under the Sales Agreement.

The Company continues to have discussions with current and prospective customers for many active programs in its commercial pipeline and has executed several agreements featuring a combination of revenue streams including exclusivity fees, device customization programs, and supply contracts that have begun to generate cash payments to the Company. The Company expects to continue to execute agreements and generate additional cash payments during the fourth quarter of fiscal year 2015. Given the substantial size, complexity, and long-term duration of many of these prospective agreements, some can take a significant amount of time to negotiate and finalize.

The Company estimates that its cash and cash equivalents, along with its restricted cash, together with the additional proceeds from the First Amendment to the Credit Agreement, proceeds raised under the Sales Agreement, and additional proceeds raised from the underwritten registered public offering, combined with anticipated cash to be generated from new and existing customer agreements are expected to provide the Company with sufficient liquidity for the next 12 months. However, there can be no assurance that such cash from customer agreements will be available when needed. These factors continue to raise substantial doubt about the Company’s 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.

### **3. 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 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 and share-based compensation expense. 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.

#### ***Inventories***

Inventories consist primarily of syringe components and include direct materials, direct labor and manufacturing overhead. Inventories are stated at the lower of cost or market, with cost determined using the first in, first out method. The Company routinely reviews its inventory for obsolete, slow moving or otherwise impaired inventory and records the estimated impact in the periods in which they occur.

#### ***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. Revenue from industrialization and development fees is recognized as services are rendered 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 and 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 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 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.

### ***Interest Expense***

The Company recognizes interest expense in the consolidated statement 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.

### ***Reclassifications***

Certain prior year amounts in the consolidated financial statements have been reclassified to conform to the current year presentation.

### ***Recently Issued Accounting Pronouncements***

In May 2014, the FASB issued ASU 2014-09 “Revenue from Contracts with Customers”. 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 for the Company, July 1, 2018. Early application is not permitted, but the standard permits the use of either the retrospective or cumulative effect transition method. The Company has not selected a transition method and is currently evaluating the impact this guidance will have on its financial condition, results of operations and cash flows.

In June 2014, FASB issued 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 beginning after December 15, 2015. The guidance can be applied prospectively for all awards granted or modified after the effective date or retrospectively to all awards with performance targets outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The Company does not expect a material impact on its financial condition, results of operations or cash flows from the adoption of this guidance.

In August 2014, the 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 April 2015, the FASB issued ASU 2015-03 “Simplifying the Presentation for Debt Issuance Costs”. The guidance requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The Company is currently evaluating the impact this guidance will have on its financial statement presentation and any disclosures.

## **4. Equity Transactions and Share-Based Compensation**

In February 2015, the Company issued 12,650,000 shares of common stock and raised \$44.7 million, net of issuance costs, through an underwritten registered public offering. The Company intends to use the proceeds from the public offering for investments in its plant, equipment, systems and personnel to further develop its manufacturing and operational capabilities to satisfy current and future customer orders and for working capital and other general corporate purposes.

The Company recognized share-based compensation expense related to equity awards to employees, directors, consultants and service providers of \$3.1 million and \$1.6 million during the three months ended March 31, 2015 and 2014, respectively and \$7.8 million and \$6.9 million during the nine months ended March 31, 2015 and 2014, respectively.

### ***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. Additionally, certain stock options vest upon the closing price of the Company’s common stock reaching certain minimum levels, as defined in the agreements. 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 6,000,000 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 1<sup>st</sup> thereafter, through January 1, 2014, the share reserve automatically adjusted so that it equals 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 10.0 million and to reapprove the Amended Stock Plan for purposes of refreshing the stockholder approval requirement.

The following is a summary of activity related to stock options held by employees and directors during the nine months ended March 31, 2015:

	<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, 2014	3,922,411	\$ 4.67		
Canceled	(97,436)	5.10		
Expired	(1,134,000)	6.35		
Outstanding as of March 31, 2015	<u>2,690,975</u>	<u>3.95</u>	<u>6.3</u>	<u>\$ 1,557</u>
Exercisable as of March 31, 2015	<u>2,003,471</u>	<u>\$ 4.09</u>	<u>5.8</u>	<u>\$ 996</u>

The following is a summary of activity related to stock options and warrants held by persons other than employees and directors during the nine months ended March 31, 2015:

	<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, 2014	2,050,000	\$ 4.53		
Expired	(1,000,000)	4.87		
Outstanding as of March 31, 2015	<u>1,050,000</u>	<u>\$ 4.20</u>	<u>1.5</u>	<u>\$ 573</u>
Exercisable as of March 31, 2015	<u>1,050,000</u>	<u>\$ 4.20</u>	<u>1.5</u>	<u>\$ 573</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. The total intrinsic value of stock options exercised during the nine months ended March 31, 2015 and 2014 was \$0 and \$1.9 million, respectively.

The Company used the following weighted average assumptions in calculating the fair value of options granted during the nine months ended March 31, 2014:

	Nine Months Ended March 31, 2014
Number of stock options granted	300,000
Expected dividend yield	0%
Risk-free interest rate	1.54%
Expected volatility	55%
Expected life (in years)	5.0

The fair value of each stock option was estimated at the grant date using the Black-Scholes option pricing model. The Company has not historically paid dividends to its stockholders and, as a result, assumed a dividend yield of 0%. The risk free interest rate is based upon the rates of U.S. Treasury bonds with a term equal to the expected term of the option. The expected volatility used to value options granted after January 27, 2010 is based upon a blended rate of the historical share price of the Company's stock on the Australian Securities Exchange and the volatility of peer companies traded on U.S. exchanges operating in the same industry as the Company. The expected term of the options to purchase common stock issued to employees and directors is based upon the simplified method, which is the mid-point between the vesting date of the option and its contractual term unless a reasonable alternate term is estimated by management. The expected term of the options to purchase common stock issued to consultants and service providers is based on the contractual term of the awards.

### ***Restricted Stock***

The Company has granted shares of restricted stock to certain employees, directors and consultants under the Amended 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.

On November 13, 2014, the shareholders approved the issuance of 4,000,000 shares of restricted stock to the Company's Chairman and Chief Executive Officer. The restricted stock was granted on November 14, 2014 and is subject to performance-based vesting and also contains service-based clawback provisions. The performance-based vesting will become satisfied based upon the trading price of the Company's common stock reaching certain minimum levels on NASDAQ for a minimum of 20 out of 30 consecutive trading days, which range from \$6.00 to \$12.00 per share. The restricted stock was valued at \$1.885 per share on the grant date using a Monte Carlo simulation model which is being expensed ratably over the projected vesting period, which is approximately 2.6 years. The restricted stock would be forfeited to the extent not vested on the fifth anniversary of the grant date. In addition, if prior to the fourth anniversary of the grant date he resigns from employment or is terminated for cause, a specified percentage of the previously vested shares would be required to be returned, which ranges from 100% prior to the first anniversary of the grant date to 25%, on or after the third anniversary of the grant date.

The following is a summary of activity related to restricted stock awards during the nine months ended March 31, 2015:

	Number of Restricted Stock Awards	Weighted Average Grant Date Fair Value
Unvested as of July 1, 2014	2,436,061	\$ 3.42
Granted	9,247,434	2.81
Vested	(612,446)	3.59
Cancelled	(214,375)	3.33
Unvested as of March 31, 2015	10,856,674	\$ 2.90

## 5. Property, Plant and Equipment and Construction-in-Progress

Property, plant and equipment consist of the following:

	<u>March 31, 2015</u>	<u>June 30, 2014</u>
	(in thousands)	
Building	\$ 32,359	\$ 32,188
Machinery and equipment	23,908	21,224
Computer software	2,832	2,675
Furniture and fixtures	613	610
Construction in progress	16,682	9,119
Land	2,036	2,036
Leasehold improvements	170	166
	<u>78,600</u>	<u>68,018</u>
Less: accumulated depreciation and amortization	<u>(16,569)</u>	<u>(13,430)</u>
Property, plant and equipment, net	<u>\$ 62,031</u>	<u>\$ 54,588</u>

Construction in progress as of March 31, 2015 consisted primarily of amounts incurred in connection with machinery and equipment including interest expense incurred during the construction phase of the related machinery and equipment. Interest capitalized during the three and nine month periods ended March 31, 2015 was \$0.5 million and \$1.5 million, respectively.

## 6. Goodwill

The changes in the carrying amount of goodwill during the nine months ended March 31, 2015 are as follows:

	(in thousands)
Balance as of July 1, 2014	\$ 11,830
Foreign currency translation	(2,104)
Balance as of March 31, 2015	<u>\$ 9,726</u>

## 7. Accrued Expenses

Accrued expenses consist of the following:

	<u>March 31, 2015</u>	<u>June 30, 2014</u>
	(In thousands)	
Accrued payroll and other employee related expenses	\$ 4,537	\$ 2,103
Accrued other	1,222	1,236
Total accrued expenses	<u>\$ 5,759</u>	<u>\$ 3,339</u>

## 8. Long-Term Debt

Long-term debt consists of the following:

	<u>March 31, 2015</u>	<u>June 30, 2014</u>
	(In thousands)	
10.25% Term loan, due March 2020	\$ 54,962	\$ 33,457
Royalty agreement liability	9,950	6,400
6.00% Mortgage loan, due December 2031	12,918	13,228
5.00% Commonwealth of Pennsylvania financing authority loan, due January 2021	2,047	2,087
Other	163	276
	<u>80,040</u>	<u>55,448</u>
Less: current portion of long-term debt	<u>904</u>	<u>613</u>
Total long-term debt	<u>\$ 79,136</u>	<u>\$ 54,835</u>

### Term Loan

On March 12, 2014, or the Closing Date, the Borrower entered into the Credit Agreement with the Lender. 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. A first tranche loan of \$40.0 million was drawn on the Closing Date 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.

The Loans bear interest at 9.25% per annum plus the greater of three-month LIBOR or 1.0%, payable in cash quarterly in arrears 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 will be interest-only until March 12, 2020 (the "Maturity Date").

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 Maturity Date. 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 ("USML") 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, USML, 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, USML, 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, as well as for the six-month period ending June 30, 2015, maintaining minimum liquidity targets, 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, USML and Unitract Syringe in accordance with the terms of the OrbiMed Credit Agreement and the related security agreements. The Company is in compliance with all the loan covenants set forth in the Amended Credit Agreement. However, there can be no assurance that the Company will be able to maintain the minimum liquidity target or achieve the minimum cash revenue covenants during the 12-month period from March 31, 2015, including the cash revenue covenant for the six month period ending June 30, 2015.

In connection with the Credit Agreement, the Borrower entered into a royalty agreement (the "Royalty Agreement") with ROS which will entitle ROS to receive royalty payments. Concurrent with the First Amendment to the Credit Agreement, the Borrower entered into the First Amendment to the Royalty Agreement. Pursuant to and subject to the terms of the Amended Royalty Agreement, Borrower has agreed to pay the Lender 3.875% on the first \$50.0 million of net sales (on a cash receipts basis as defined in the Amended Credit Agreement) in each fiscal year, plus 1.500% of net sales in excess of \$50.0 million and up to and including \$100.0 million in each fiscal year, plus 0.375% of net sales in excess of \$100.0 million in each fiscal year. Borrower has the right to buyout the Amended Royalty Agreement at any time on or before March 12, 2018 at a reduced amount. The lender has the right to exercise a put option upon the occurrence of an event of default upon which the Borrower would be required to pay the buyout amount under the Amended Royalty Agreement. The buy-out amount ranges from \$9.75 million to \$26.25 million (such amount to be determined based on when the buy-out or put option is exercised), less amounts previously paid by Borrower to

Lender pursuant to the Amended Royalty Agreement. The Amended Royalty Agreement has a term commencing on the Closing Date and ending on the earlier of (i) the tenth anniversary of the Closing Date 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.

The Company determined that the Credit Agreement and the 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 the Closing Date, the Royalty liability was determined to have a fair value of \$7.0 million and the Loan was allocated the remaining proceeds of \$33.0 million. The \$20.0 million from the two additional tranches that were funded during the three months ended December 31, 2014 was reflected as incremental debt. The Loan 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 March 31, 2015, the fair value of the Royalty liability was \$10.0 million.

There are cross-defaults in the OrbiMed Amended Credit Agreement, Metro Bank Loan and Keystone/CFA Loan, so that a default under one agreement could trigger a default under the others. Metro Bank, the Lender under the OrbiMed Amended Credit Agreement, Keystone Redevelopment Group, LLC and Commonwealth Financing Authority are parties to an intercreditor agreement.

### **Mortgage Loan**

In October 2010, Cross Farm entered into the Loan Agreement with Metro Bank, pursuant to which Metro 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 Metro Loan Document contains 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 sheet, which will remain in place until Cross Farm and Metro agree on the financial covenants. The terms of the Original Metro 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 March 31, 2015. 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 March 31, 2015. 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 Metro 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 the Commonwealth of Pennsylvania 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. In connection with the loan agreement, 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.



## 9. Net Loss Per Share

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2015	2014	2015	2014
(In thousands, except share and per share data)				
<b>Numerator</b>				
Net loss	\$ (23,105)	\$ (15,109)	\$ (64,754)	\$ (42,636)
<b>Denominator</b>				
Weighted average number of shares used to compute basic net loss per share	115,821,411	100,007,135	109,319,142	97,135,688
Effect of dilutive options to purchase common stock	—	—	—	—
Weighted average number of shares used to compute diluted net loss per share	115,821,411	100,007,135	109,319,142	97,135,688
<b>Basic and diluted net loss per share</b>	<u>\$ (0.20)</u>	<u>\$ (0.15)</u>	<u>\$ (0.59)</u>	<u>\$ (0.44)</u>

Due to the Company's net losses, unvested shares of restricted stock (participating securities) totaling 9,244,627 and 2,564,631 were excluded from the calculation of basic and diluted net loss per share during the three months ended March 31, 2015 and 2014, respectively, and unvested shares of restricted stock (participating securities) totaling 5,716,086 and 2,774,977 were excluded from the calculation of basic and diluted net loss per share during the nine months ended March 31, 2015 and 2014, respectively.

In addition, stock options (non-participating securities) totaling 3,461,911 and 3,429,685 during the three months ended March 31, 2015 and 2014, respectively, were excluded from the calculation of diluted net loss per share and stock options (non-participating securities) totaling 3,596,242 and 4,985,648 during the nine months ended March 31, 2015 and 2014, 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 March 31, 2015 and 2014, these shares would have had an effect of 354,758 and 493,490 diluted shares, respectively, for purposes of calculating diluted net income per share. Had the Company reported net income during the nine months ended March 31, 2015 and 2014, these shares would have had an effect of 167,459 and 398,727 diluted shares, respectively, for purposes of calculating diluted net income per share.

## 10. 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 not probable that an unfavorable outcome will result.

On September 7, 2012, the Company received a letter from counsel for Talbot (Todd) Smith, a former employee, alleging that Mr. Smith was wrongly terminated. Mr. Smith, who was terminated "for cause" by the Company, filed a complaint with the U.S. Occupational Safety and Health Administration (OSHA) in November 2012. The Company and various third parties have investigated the allegations made by Mr. Smith and have determined that his allegations are without merit. The Company believes the allegations made by Mr. Smith against it are in retaliation for his "for cause" termination and defended itself vigorously in the OSHA matter. Because OSHA did not make a final determination on Mr. Smith's complaint within 180 days, Mr. Smith filed a civil complaint in the United States District Court for the Eastern District of Pennsylvania on August 30, 2013 and an amended complaint on March 5, 2014 against the Company and various officers of the Company. OSHA accordingly dismissed the OSHA matter without a final determination. The complaint filed in the District Court makes the same allegations made by Mr. Smith in the OSHA complaint and also includes a defamation claim. To the extent that the allegations made by Mr. Smith in the District Court are nearly identical to those made in his OSHA complaint, the Company and various third parties have investigated his allegations previously and have determined that the allegations are without merit, and the Company intends to defend itself vigorously in the District Court action. After Mr. Smith disclosed a violation of the Pennsylvania Wire Tapping and Electronic Surveillance Control Act (PA Wiretapping Act) during the pendency of discovery in the District Court action, on June 20, 2014 the Company filed counterclaims

against Mr. Smith for his violation of the PA Wiretapping Act. Discovery has concluded and in February 2015 the Company filed its motions for summary judgment with the District Court, seeking entry of judgment in favor of the Company on the claims brought by Mr. Smith against the Company, and entry of judgment in favor of the Company on the claims brought by the Company against Mr. Smith. Those motions are currently pending before the District Court.

As previously disclosed, subsequent to the filing of the OSHA complaint by Mr. Smith, the Company received a subpoena from the staff of the U.S. Securities and Exchange Commission (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 states 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 from the Staff, requesting additional information consistent with the first subpoena. The Company is cooperating fully with the Staff and is providing the requested information.

On January 8, 2014, the Company was served with a derivative complaint filed in the Delaware Chancery Court by Cambridge Retirement System, a purported stockholder of the Company, against its Board of Directors to recover allegedly “excessive and wasteful” compensation paid to the non-executive directors since 2010. The Company believes that these allegations are baseless and without merit and the Company and the directors are defending themselves vigorously. In February 2014, the Company filed a motion to dismiss the complaint in lieu of an answer. On June 26, 2014, the Court granted the Company’s motion to dismiss 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 on July 11, 2014. The action is currently in discovery.

The Company does not believe there will be any material impact to the Company or its business as a result of these matters.

## 11. Revenue

The Company recognized \$2.9 million and \$1.4 million of revenue during the three months ended March 31, 2015 and 2014, respectively. The Company recognized \$9.7 million and \$8.1 million of revenue during the nine months ended March 31, 2015 and 2014, respectively.

During the three months ended March 31, 2015 three customers accounted for 31%, 28% and 19% of consolidated revenue, respectively. During the three months ended March 31, 2014 two customers accounted for 57%, and 16% of consolidated revenue, respectively. During the nine months ended March 31, 2015 two customers accounted for 42% and 33% of consolidated revenue, respectively. During the nine months ended March 31, 2014 four customers accounted for 32%, 29%, 16% and 10% of consolidated revenue, respectively.

During the three and nine months ended March 31, 2015, the Company recognized \$0.6 million and \$3.7 million of revenue, respectively, related to substantive milestones, as follows:

The Company recognized \$0.0 million and \$2.3 million of revenue during the three and nine months ended March 31, 2015, respectively, pursuant to a feasibility agreement with a customer related to substantive milestones that were completed and accepted during the respective periods. 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 determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the nine months ended March 31, 2015 are as follows:

- \$0.4 million for development and delivery of a detailed project plan and a failure mode and effects analysis report;
- \$0.4 million for development and delivery of a report on preliminary product requirements and a risk management plan; and
- \$1.5 million for development and delivery of human factor stimuli and related supporting documents.

The remaining substantive milestones as of March 31, 2015 were as follows:

- \$0.4 million for development and delivery of additional human factor stimuli;
- \$0.5 million for development and delivery of additional human factor stimuli and a report on updated product requirements; and
- \$1.2 million for development and delivery of semi-functional prototypes and related feasibility, product requirement, and risk management reports.

The Company recognized \$0.5 million and \$0.9 million of revenue during the three and nine months ended March 31, 2015, respectively, pursuant to a feasibility agreement with a customer related to substantive milestones that was completed and accepted during the respective periods. 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 \$0.45 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 and nine months ended March 31, 2015 are as follows:

- \$0.5 million for development and delivery of a report on device design options as well as potential manufacturing and assembly processes; and
- \$0.5 million for development and delivery of product samples and related supporting documents.

The remaining substantive milestone as of March 31, 2015 was as follows:

- \$0.2 million for development and delivery of a summary report related to testing and documentation activities.

The Company recognized \$0.1 million and \$0.3 million of revenue during the three and nine months ended March 31, 2015, respectively, pursuant to a feasibility agreement with a customer related to substantive milestones that were completed and accepted during the respective periods. 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. The milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the three and nine months ended March 31, 2015 are as follows:

- \$0.1 million for development and delivery of a report related to human factor studies and quality requirements;
- \$0.1 million for development and delivery of devices for compatibility and stability functional testing and related reporting; and
- \$0.1 million for development and delivery of devices for human factor study and related reporting.

There are no remaining substantive milestones under this agreement.

The Company recognized \$0.0 million and \$0.2 million of revenue during the three and nine months ended March 31, 2015, respectively, pursuant to a feasibility agreement with a customer related to substantive milestones that were completed and accepted during the respective periods. 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. The milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the nine months ended March 31, 2015 are as follows:

- \$0.1 million for development of customized devices for testing; and
- \$0.1 million for development and delivery of testing activities and related reporting.

There are no remaining substantive milestones under this agreement.

During the three and nine months ended March 31, 2015, the Company recognized \$2.3 million and \$6.0 million, respectively, 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.

During the three and nine months ended March 31, 2014, the Company recognized \$0.4 million and \$2.9 million of revenue, respectively, related to substantive milestones, as follows:

The Company recognized \$0.1 million and \$1.3 million of revenue during the three and nine months ended March 31, 2014, respectively, pursuant to a clinical supply agreement with a customer related to substantive milestones that were completed and accepted during the respective periods. This agreement provides for the customization and development activities for a drug delivery system for a customer and provides for payments to be made upon the completion of agreed-upon milestones. The milestones were determined to be substantive at the time the agreement was entered into. Substantive milestones that were achieved during the three and nine months ended March 31, 2014 are as follows:

- \$0.4 million for development and delivery of devices to be used by the customer for compatibility testing;
- \$0.1 million for delivery of development and testing activities;
- \$0.6 million for delivery of development, testing and verification activities;
- \$0.1 million for development and delivery of testing materials;
- \$0.2 million for development and delivery of qualification and software programming activities; and
- \$0.1 million for certain support and testing activities.

There are no remaining substantive milestones under this agreement.

The Company recognized \$0.0 and \$0.8 million of revenue during the three and nine months ended March 31, 2014, respectively, pursuant to a customization and commercial supply agreement with a customer related to a substantive milestone that was completed during the respective periods. This agreement provides for the development of customized component parts for the customer to use in a drug-device combination product and provides for payments to be made upon the completion of agreed-upon milestones. The milestones were determined to be substantive at the time the agreement was entered into. The substantive milestone achieved during the three and nine months ended March 31, 2014 was as follows:

- \$0.8 million for customization and delivery of devices for compatibility and initial evaluation testing.

The remaining substantive milestones were as follows:

- \$0.8 million for delivery of devices for regulatory filings; and
- \$0.2 million for certain delivery of services supporting the customer's regulatory approval process.

The Company recognized \$0.2 million and \$0.7 million of revenue during the three and nine months ended March 31, 2014, respectively, pursuant to a materials transfer agreement with a customer related to substantive milestones that were completed during the respective periods. This agreement provides for certain materials and related services to the customer and provides for payments to

be made upon the completion of agreed-upon milestones. The milestones were determined to be substantive at the time the agreement was entered into. The substantive milestone achieved during the three and nine months ended March 31, 2014 was as follows:

- \$0.4 million for delivery of testing materials;
- \$0.1 million for delivery of device design requirements report; and
- \$0.2 million for delivery of customization activities.

There were no remaining substantive milestones under this agreement.

The Company recognized \$0.1 million and \$0.1 million of revenue during the three and nine months ended March 31, 2014, respectively, pursuant to a collaborative research agreement with a customer related to a substantive milestone that was completed during the respective periods. This agreement provides for certain materials and related services to the customer and provides for payments to be made upon the completion of agreed-upon milestones. The milestones were determined to be substantive at the time the agreement was entered into. The substantive milestone achieved during the three and nine months ended March 31, 2014 was as follows:

- \$0.1 million for customization and delivery of devices for evaluation and user study purposes.

The remaining substantive milestones was as follows:

- \$0.2 million for customization and delivery of devices for evaluation activities.

During the three and nine months ended March 31, 2014, the Company recognized \$1.0 million and \$2.9 million, respectively, in revenue related to services rendered on a time and materials basis during the period pursuant to customer agreements to provide various customization and development services. During the nine months ended March 31, 2014, the Company recognized the final \$2.3 million of revenue related to its licensing agreement with Sanofi.

## 12. Financial Instruments

The Company does not hold or issue financial instruments for trading purposes. The estimated fair values of the Company's financial instruments are as follows:

	March 31, 2015		June 30, 2014	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
	(In thousands)			
Royalty agreement liability	\$ 9,950	\$ 9,950	\$ 6,400	\$ 6,400

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.

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:

	Fair Value Based On			Total Fair Value Measurements
	Quoted Market Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
	(In thousands)			
Royalty Agreement liability as of March 31, 2015	\$ —	\$ —	\$ 9,950	\$ 9,950

The following table presents the changes in the fair value of the level 3 financial instruments for the nine months ended March 31, 2015. There were no level 3 financial instruments for the nine months ended March 31, 2014:

	Royalty Agreement Liability
June 30, 2014	\$ 6,400
Royalty payments	(403)
Increase in royalty liability	3,953
March 31, 2015	\$ 9,950

Following is a description of the valuation methodology used to measure the Royalty Agreement liability at fair value. There have been no changes in the methodology used during the nine months ended March 31, 2015:

The fair value 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.

## **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 our Annual Report on Form 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 our Annual Report on Form 10-K and those described from time to time in other reports which we file with the Securities and Exchange Commission.

### **Overview**

We are a designer, manufacturer and supplier of innovative injectable drug delivery systems that can enhance and differentiate the injectable therapies of our customers. We have a broad portfolio of proprietary product platforms, including pre-filled syringes, drug reconstitution delivery systems, auto-injectors, wearable injectors, ocular delivery systems and other novel injectable drug delivery systems. Products within each platform are highly differentiated from competitors' products with a series of innovative features designed to optimize the safe, simple and convenient administration of an injectable therapy. We sell our products directly to pharmaceutical and biotechnology companies who incorporate them into the drug-device combination product that is supplied pre-filled and ready for administration by end-users such as health-care providers or patients. Products within each of our platforms can be customized by us to address specific customer, therapy, patient and/or commercial requirements.

### **Key Factors Affecting Performance and Financial Condition**

We have entered into several agreements with our customers including customers with whom we have entered into a customization or supply agreement and customers with whom we have entered into preliminary agreements such as letters of intent. 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 and nine month periods ended March 31, 2015. We also increased expenses during the three and nine month periods ended March 31, 2015 as a result of investments in expanding our manufacturing capacity and increased research and development efforts, both in response to increasing demand from our customers for our products and services.

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. In recent years we have addressed our capital needs through the use of an "At-The-Market" equity offering, pursuant to which we, from time to time, issued and sold shares of common stock having an aggregate offering price of \$45.0 million, customization, industrialization and development fees received from our customers, and our debt financing from an affiliate of OrbiMed Advisors, or OrbiMed, in March 2014. In February 2015, we issued 12,650,000 shares of common stock and raised \$44.7 million, net of issuance costs, through an underwritten registered public offering.



## ***Revenue***

Our revenue is currently generated from customization, industrialization, licensing and development 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 and nine month periods ended March 31, 2015. Product sales historically have not had a meaningful impact on our revenue, however, we expect over time they will begin to account for an increasing portion of our revenue as we increase commercial sales to customers.

We expect our revenue to increase overtime, as we continue to deliver under our existing contracts with our customers and enter into additional agreements with new and existing customers, however, our revenue could fluctuate on a quarter to quarter basis. We also expect that our future revenue will be favorably impacted by several trends in the industry, including 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.

## ***Operating Expenses***

Our operating expenses have increased primarily as a result of the increased research and development efforts, both in response to increasing demand from our customers for our products and services. We increased our cross-functional research and development teams of engineers and other staff that are dedicated to servicing existing and prospective customers. The increase in research and development costs also related to the costs of products and components supplied to existing and prospective customers to support evaluation processes and user studies that are typically undertaken prior to the anticipated signing of customer agreements.

## ***Significant Developments in the Industry***

We believe that recently signed customer contracts and future customer contracts expected to be signed with existing and prospective customers, as a result of ongoing discussions, 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 many of our products, including prefilled syringes, drug reconstitution delivery systems, auto-injectors, and wearable injectors, are well suited for safe and intuitive patient self-administration of injectable therapies and that we will be able to meet the expected increase in demand for such products.

## **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 our Annual Report on Form 10-K. There have been no changes in critical accounting policies in the current year from those described in our Annual Report on Form 10-K.

## **Basis of Presentation**

### ***Revenue***

We derive revenue primarily from customization, industrialization and development programs with our customers. 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 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 marketing and commercial development costs, quality assurance and regulatory costs, accounting and financial related costs, information and technology costs, legal and professional fees, corporate facility costs, corporate payroll and related benefit costs (including share-based compensation expense).

### ***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 up to 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.

### ***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 and nine months ended March 31, 2015 and 2014:

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2015	2014	2015	2014
	(in thousands, except per share data)			
Revenue	\$ 2,921	\$ 1,383	\$ 9,704	\$ 8,143
Research and development	13,213	8,018	35,498	22,224
Selling, general and administrative	9,055	6,649	26,763	19,872
Depreciation and amortization	1,184	1,026	3,537	3,068
Total operating expenses	23,452	15,693	65,798	45,164
Operating loss	(20,531)	(14,310)	(56,094)	(37,021)
Interest expense	1,796	809	4,710	5,640
Change in fair value of financial instruments	783	—	3,953	—
Other income, net	(5)	(10)	(3)	(25)
Net loss	<u>\$(23,105)</u>	<u>\$(15,109)</u>	<u>\$(64,754)</u>	<u>\$(42,636)</u>
<b>Net loss per share:</b>				
Basic and diluted net loss per share	<u>\$ (0.20)</u>	<u>\$ (0.15)</u>	<u>\$ (0.59)</u>	<u>\$ (0.44)</u>

### Three Months Ended March 31, 2015 Compared to Three Months Ended March 31, 2014

**Revenue.** Revenue increased by \$1.5 million or 111.2%. During the three months ended March 31, 2015, we recognized approximately \$0.6 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. Substantive milestones completed during the period included various customization activities, device design, devices developed for use in customer evaluation testing, compatibility testing, user studies, and verification activities. During the three months ended March 31, 2015, we recognized \$2.3 million in revenue related to services rendered on a time and materials basis, proportional performance method and straight line basis over the requisite service period pursuant to customer agreements to provide various customization and development services. During the three months ended March 31, 2014, we recognized approximately \$0.4 million of revenue related to substantive milestones that were completed during the period and \$1.0 million in revenue related to services rendered on a time and materials basis during the period pursuant to customer agreements to provide various customization and development services. We expect future revenue to continue to increase over time as we deliver under the customer agreements we have previously entered into and from additional customer agreements that we expect to enter into in future periods; however, our revenue could fluctuate on a quarter to quarter basis.

**Research and development expenses.** Research and development expenses increased by \$5.2 million or 64.8% primarily due to increased payroll and related costs of \$2.3 million related to increased headcount to support ongoing and future customer programs, increased material and tooling costs of \$2.3 million, and increased share-based compensation expense of \$0.5 million. The increased investment in research and development during the current period is related to the supply of products and components to existing customers including for customization, industrialization and development programs and prospective customers to support evaluation processes and user studies that are typically undertaken prior to the anticipated signing of contracts. We expect to continue our investment in research and development as we service existing customers and enter into additional customer agreements in future periods.

**Selling, general and administrative expenses.** Selling, general and administrative expenses increased by \$2.4 million or 36.2% primarily due to increased legal and professional fees of \$0.5 million, increased share-based compensation expense of \$1.0 million, increased payroll and related costs of \$0.4 million and increased other administrative costs of \$0.5 million.

**Depreciation and amortization expense.** Depreciation and amortization expense increased by \$0.2 million or 15.4% primarily as a result of additional equipment previously placed in service.

**Interest expense.** Interest expense increased by \$1.0 million or 122.0% primarily attributable to interest on the OrbiMed financing, partially offset by \$0.5 million of interest which was capitalized.

**Change in fair value of financial instruments.** Change in fair value of financial instruments increased by \$0.8 million in the current quarter. The increase is related to the change in the fair value of the Royalty liability in connection with the OrbiMed financing which is revalued each quarter.

**Net loss and net loss per share.** Net loss during the three months ended March 31, 2015 and 2014 was \$23.1 million and \$15.1 million, respectively. Basic and diluted net loss per share was \$0.20 and \$0.15, respectively, on weighted average shares outstanding of 115,821,411 and 100,007,135. The increase in the weighted average shares outstanding was primarily due to the issuance of common stock in connection with shares issued under the Sales Agreement as well as shares issued in our public offering in February 2015.

#### **Nine Months Ended March 31, 2015 Compared to Nine Months Ended March 31, 2014**

**Revenue.** Revenue increased by \$1.6 million or 19.2%. During the nine months ended March 31, 2015, we recognized approximately \$3.7 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. Substantive milestones completed during the period included various customization activities, device design, devices developed for use in customer evaluation testing, compatibility testing, user studies, and verification activities. During the nine months ended March 31, 2015, we recognized \$6.0 million in revenue related to services rendered on a time and materials basis, proportional performance method and straight line basis over the requisite service period pursuant to customer agreements to provide various customization and development services. During the nine months ended March 31, 2014, we recognized approximately \$2.9 million of revenue related to substantive milestones that were completed during the period and \$2.9 million in revenue related to services rendered on a time and materials basis during the period pursuant to customer agreements to provide various customization and development services. Also during the nine month period ended March 31, 2014, we recognized \$2.3 million of revenue related to our former agreement with Sanofi.

**Research and development expenses.** Research and development expenses increased by \$13.3 million or 59.7% primarily due to increased payroll and related costs of \$5.6 million related to increased headcount to support ongoing and future customer programs, increased material and tooling costs of \$5.6 million, and increased other research and development costs of \$2.1 million. The increased investment in research and development during the current period is related to the supply of products and components to existing customers including for customization, industrialization and development programs and prospective customers to support evaluation processes and user studies that are typically undertaken prior to the anticipated signing of contracts. We expect to continue our investment in research and development as we service existing customers and enter into additional customer agreements in future periods.

**Selling, general and administrative expenses.** Selling, general and administrative expenses increased by \$6.9 million or 34.7% primarily due to increased legal and professional fees of \$2.7 million, increased payroll and related costs of \$1.5 million, increased share-based compensation expense of \$1.2 million and increased other administrative costs of \$1.5 million.

**Depreciation and amortization expense.** Depreciation and amortization expense increased by \$0.5 million or 15.3% primarily as a result of additional equipment previously placed in service.

**Interest expense.** Interest expense decreased by \$0.9 million or 16.5% primarily attributable to the settlement agreement with Varilease in the prior year period of \$3.9 million as well as \$2.3 million as a result of debt which was refinanced and interest which was capitalized. These decreases were partially offset by interest on the OrbiMed financing of \$5.3 million.

**Change in fair value of financial instruments.** Change in fair value of financial instruments increased by \$4.0 million in the current period. The increase is related to the change in the fair value of the Royalty liability in connection with the OrbiMed financing which is revalued each quarter.

**Net loss and net loss per share.** Net loss during the nine months ended March 31, 2015 and 2014 was \$64.8 million and \$42.6 million, respectively. Basic and diluted net loss per share was \$0.59 and \$0.44, respectively, on weighted average shares outstanding of 109,319,142 and 97,135,688. The increase in the weighted average shares outstanding was primarily due to the issuance of common stock in connection with shares issued under the Sales Agreement.

## **Liquidity and Capital Resources**

To date, we have funded our operations primarily from a combination of term loans, equity issuances, borrowings under our bank mortgages, and payments from various customers. As of March 31, 2015, cash and cash equivalents were \$37.1 million, restricted cash was \$2.1 million and our long-term debt was \$80.0 million. As of June 30, 2014, cash and cash equivalents were \$8.4 million, restricted cash was \$2.4 million and our long-term debt was \$55.4 million. The restricted cash relates to amounts that must remain in cash deposits under our loan agreement with Metro Bank.

In February 2015, we issued 12,650,000 shares of common stock and raised \$44.7 million, net of issuance costs, through an underwritten registered public offering.

On March 12, 2014, we entered into the Credit Agreement with an affiliate of OrbiMed Advisors (“Lender”). Under the terms of the Credit Agreement, the Lender agreed to provide term loans to us in the aggregate principal amount of up to \$60.0 million. A first tranche loan of \$40.0 million was drawn on the Closing Date 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 we entered into a First Amendment to the Credit Agreement pursuant to which we 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. Under the Amended Credit Agreement, Borrower’s prepayments and repayments of any unpaid principal amount of the Loans shall include a 10.0% repayment premium (with certain enumerated exceptions). The Amended Credit Agreement contains customary representations and warranties in favor of the Lender. The Amended Credit Agreement also contains certain covenants relating to financial performance, liquidity targets among others. The Company is in compliance with all the loan covenants set forth in the Amended Credit Agreement. However, there can be no assurance that the Company will be able to maintain the minimum liquidity target or achieve the minimum cash revenue covenants during the 12-month period from March 31, 2015, including the cash revenue covenant for the six month period ending June 30, 2015.

Concurrent with the First Amendment to the Credit Agreement, we entered into the First Amendment to the Royalty Agreement. Pursuant to and subject to the terms of the Amended Royalty Agreement, Borrower has agreed to pay the Lender 3.875% on the first \$50.0 million of net sales in each fiscal year, plus 1.500% of net sales in excess of \$50.0 million and up to and including \$100.0 million in each fiscal year, plus 0.375% of net sales in excess of \$100.0 million in each fiscal year. Borrower has the right to buyout the Amended Royalty Agreement at any time on or before March 12, 2018 at a reduced amount. The buy-out amount ranges from \$9.75 million to \$26.25 million (such amount to be determined based on when the buy-out option is exercised), less amounts previously paid by Borrower to Lender pursuant to the Amended Royalty Agreement.

During October 2012, we entered into the Sales Agreement, pursuant to which we may, from time to time, issue and sell shares of common stock having an aggregate offering price of up to \$45.0 million. During the nine months ended March 31, 2015, we issued 5,808,800 shares of common stock and raised approximately \$12.4 million under the Sales Agreement, which was the full remaining amount available for sale under the Sales Agreement. As a result, we have completed use of the full facility available under the Sales Agreement.

We have incurred losses from operations during the year ended June 30, 2014 and nine months ended March 31, 2015 and anticipate incurring additional losses until such time that we can generate sufficient revenue from the sale, customization or exclusive use and licensing of our proprietary range of injectable drug delivery systems to pharmaceutical and biotechnology customers.

We continue to have discussions with current and prospective customers for many active programs in our commercial pipeline and have executed several agreements featuring a combination of revenue streams, including exclusivity fees, device customization programs and supply contracts that have begun to generate cash payments. We expect to continue to execute agreements and generate additional cash payments during the remainder of fiscal year 2015. Given the substantial size,

complexity and long-term duration of many of these prospective agreements, some can take a significant amount of time to negotiate and finalize. We estimate that our cash and cash equivalents of \$37.1 million as of March 31, 2015, along with our \$2.1 million of restricted cash, as well as the anticipated cash receipts from customers is sufficient to sustain planned operations for the next 12 months. However, there can be no assurance that such cash from customer agreements will be available when needed.

The following table summarizes our cash flows during the nine months ended March 31, 2015 and 2014:

	Nine Months Ended March 31,	
	2015	2014
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$(36,246)	\$(12,982)
Investing activities	(11,547)	(3,377)
Financing activities	76,523	48,234

#### *Net Cash Used In Operating Activities*

Net cash used in operating activities during the nine months ended March 31, 2015 was \$36.2 million compared to \$13.0 million during the nine months ended March 31, 2014. The increase in net cash used in operating activities was primarily due to the increase in net loss during the period.

#### *Net Cash Used in Investing Activities*

Net cash used in investing activities during the nine months ended March 31, 2015 and 2014 was \$11.5 million and \$3.4 million respectively, primarily as a result of costs incurred in connection with the purchase of machinery and related equipment.

#### *Net Cash Provided by Financing Activities*

Net cash provided by financing activities during the nine months ended March 31, 2015 was \$76.5 million compared to \$48.2 million during the nine months ended March 31, 2014.

During the nine months ended March 31, 2015, we received \$44.7 million in net proceeds from our public offering of common stock in February 2015, \$20.0 million in aggregate proceeds from the two additional tranches under the Amended Credit Agreement with OrbiMed and \$12.4 million of proceeds in connection with our public offering of common stock under the Sales Agreement which was partially offset by \$0.9 million in principal debt repayments.

During the nine months ended March 31, 2014, we received \$40.0 million from our March 2014 term loan, \$16.9 million in connection with our public offering of common stock under the Sales Agreement and \$2.5 million upon the exercise of stock options. These amounts were partially offset by principal debt payments of \$11.1 million.

### **Contractual Obligations and Commitments**

The following table provides information regarding our contractual obligations as of March 31, 2015:

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years (In thousands)	3-5 Years	More Than 5 Years
Long-term debt and related interest	\$120,076	\$ 7,965	\$15,120	\$14,795	\$ 82,196
Operating leases	9,052	1,137	2,450	2,528	2,937
Purchase obligations	20,858	20,858	—	—	—
Total contractual obligations	<u>\$149,986</u>	<u>\$ 29,960</u>	<u>\$17,570</u>	<u>\$17,323</u>	<u>\$ 85,133</u>

### **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***

Our Principal Executive Officer and Principal Financial Officer, with the participation of our management, has evaluated the effectiveness of our disclosure controls and procedures (pursuant to Rule 13a-15(e) and 15d-(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by us in the reports that we file or submit under the Exchange Act and are effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

#### ***Changes in Internal Control***

There has not been any change in our internal control over financial reporting (as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

On September 7, 2012, we received a letter from counsel for Talbot (Todd) Smith, a former employee, alleging that Mr. Smith was wrongly terminated. Mr. Smith, who was terminated “for cause” by us, filed a complaint with the U.S. Occupational Safety and Health Administration, or OSHA, in November 2012. We and various third parties have investigated the allegations made by Mr. Smith and have determined that his allegations are without merit. We believe the allegations made by Mr. Smith against us are in retaliation for his “for cause” termination and defended ourselves vigorously in the OSHA matter. Because OSHA did not make a final determination on Mr. Smith’s complaint within 180 days, Mr. Smith filed a civil complaint in the United States District Court for the Eastern District of Pennsylvania on August 30, 2013 and an amended complaint on March 5, 2014 against the Company and various officers of the Company. OSHA accordingly dismissed the OSHA matter without a final determination. The complaint filed in the District Court makes the same allegations made by Mr. Smith in the OSHA complaint and also includes a defamation claim. To the extent that the allegations made by Mr. Smith in the District Court are nearly identical to those made in his OSHA complaint, we and various third parties have investigated his allegations previously and have determined that the allegations are without merit, and we intend to defend ourselves vigorously in the District Court action. After Mr. Smith disclosed a violation of the Pennsylvania Wire Tapping and Electronic Surveillance Control Act, or the PA Wiretapping Act, during the pendency of discovery in the District Court action, on June 20, 2014, we filed counterclaims against Mr. Smith for his violation of the PA Wiretapping Act. Discovery has concluded and in February 2015 we filed our motions for summary judgment with the District Court, seeking entry of judgment in favor of the Company on the claims brought by Mr. Smith against the Company, and entry of judgment in favor of the Company on the claims brought by the Company against Mr. Smith. Those motions are currently pending before the District Court.

On January 8, 2014, we were served with a derivative complaint filed in the Delaware Chancery Court by Cambridge Retirement System, a purported stockholder of the Company, against our board of directors to recover allegedly “excessive and wasteful” compensation paid to the non-executive directors since 2010. We believe that these allegations are baseless and without merit and we and the directors are defending ourselves vigorously. In February 2014, we filed a motion to dismiss the complaint in lieu of an answer. On June 26, 2014, the Court granted our motion to dismiss with respect to the directors’ equity grants, but denied the motion with respect to their cash compensation. We filed an answer to the remaining claims on July 11, 2014. The action is currently in discovery.

We do not believe there will be any material impact to us or our business as a result of either of these matters.

### Item 5. Other Information

### Item 6. Exhibits

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

<u>Exhibit No.</u>	<u>Description of Exhibit</u>	<u>Included Herewith</u>
10.1	Employment Agreement, dated January 9, 2015, by and between Unilife Corporation and David C. Hastings, incorporated by reference to the designated exhibit of the Company’s Current Report on Form 8-K filed January 14, 2015	
10.2	Offer Letter, dated January 9, 2015, by and between Unilife Corporation and David C. Hastings, incorporated by reference to the designated exhibit of the Company’s Current Report on Form 8-K filed January 14, 2015	
10.3	Amendment to Employment Agreement, dated January 9, 2015, by and between Unilife Corporation and Ramin Mojdeh, Ph.D., incorporated by reference to the designated exhibit of the Company’s Current Report on Form 8-K filed January 14, 2015	
10.4	Amendment to Employment Agreement, dated January 9, 2015, by and between Unilife Corporation and John C. Ryan, incorporated by reference to the designated exhibit of the Company’s Current Report on Form 8-K filed January 14, 2015	
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	X
32.2	Section 1350 Certification	X
101.INS	XBRL Instance Document	X
101.SCH	XBRL Taxonomy Extension Schema	X



<b><u>Exhibit No.</u></b>	<b><u>Description of Exhibit</u></b>	<b><u>Included Herewith</u></b>
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

## **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: May 11, 2015

UNILIFE CORPORATION

By: /s/ David C. Hastings

David C. Hastings  
Chief Financial Officer

**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, Alan Shortall, 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.

Date: May 11, 2015

/s/ Alan Shortall

Name: Alan Shortall

Title: Chairman and Chief Executive Officer

**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.
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.

Date: May 11, 2015

/s/ David C. Hastings

Name: David C. Hastings

Title: Chief Financial Officer

**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 of Unilife Corporation (the “Company”) on Form 10-Q for the quarterly period ended March 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Alan Shortall, 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.

Date: May 11, 2015

/s/ Alan Shortall

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Name: Alan Shortall

Title: Chairman and Chief Executive Officer

**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 of Unilife Corporation (the “Company”) on Form 10-Q for the quarterly period ended March 31, 2015 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.

Date: May 11, 2015

/s/ David C. Hastings

Name: David C. Hastings

Title: Chief Financial Officer