



November 9, 2015

Unilife Corporation Announces Financial Results For the First Quarter of Fiscal Year 2016

YORK, Pa., Nov. 9, 2015 /PRNewswire/ -- Unilife Corporation ("Unilife" or "Company") (NASDAQ:UNIS; ASX: UNS), a developer and supplier of injectable drug delivery systems, today announced its financial results for the first quarter of fiscal 2016 (ended September 30, 2015).

Morgan Stanley Process

In response to third-party initiated expressions of interest, Unilife engaged Morgan Stanley & Co. LLC as its financial advisor in September 2015 to conduct a review of strategic alternatives to maximize shareholder value. Unilife has received interest from several parties, and the Company hopes to announce a strategic transaction by December 31, 2015. Please see "Forward Looking Statements" below.

Additional Funding

Unilife today announced the direct sale to an institutional investor of 790 shares of newly designated Series A Redeemable Convertible Preferred Stock ("Series A Preferred Stock") for an aggregate face amount of \$7.9 million. The face amount of the investment is convertible into shares of the Company's common stock at a fixed conversion price of \$1.00 per share of common stock. Unilife is to receive approximately \$7.5 million in gross proceeds less expenses and accounting for an original issue discount. Additional common shares that the Company may issue, at its sole discretion in lieu of cash, as a conversion premium or in payment of dividends on such shares of Series A Preferred Stock is dependent on the dividend rate which can range from 0% to 15% depending on the Company's underlying stock price at the time of conversion, subject to adjustment. See the Form 8-K filed on November 9, 2015 for other material terms relating to this transaction and for the terms of the Series A Preferred Stock.

Debt Financing Agreement with an Affiliate of OrbiMed

The Company announced on October 16, the signing of an agreement with an affiliate of OrbiMed for the provision of up to an additional \$10 million in debt financing. As of November 6, 2015, Unilife had received \$6.9 million under this amendment. The material terms are described in a Form 8-K filing made with the SEC on October 16, 2015.

On November 6, 2015, OrbiMed agreed to waive the covenant in the Amended Credit Agreement that requires Unilife to generate \$54.1 million in customer cash receipts from January 1, 2015 to December 31, 2015. There were no other changes to the terms of the Amended Credit Agreement or Amended Royalty Agreement in connection with such waiver.

Cost Reduction Initiatives

Following the development of the Imperium™ platform of insulin patch pumps announced last month, Unilife has now established a full portfolio of products and capabilities to serve customers across all target market segments. By completing the development stage of its strategy, the Company can now focus its resources entirely on the customization and commercialization of existing products under current and prospective customer supply agreements. To support this new stage of business operations and help preserve its resources, Unilife previously announced the implementation of cost reduction and business realignment initiatives during September and October 2015 that included a reduction of its workforce of approximately 24% in the aggregate, and a decrease in compensation to executive officers and certain other senior management.

Compared to the annualized run rate for operating expenses in the fourth quarter of fiscal 2015, and excluding share-based compensation and depreciation expense, these measures are expected to decrease R&D expense by approximately 30% in fiscal 2016, and selling, general and administrative expense by approximately 20% in fiscal 2016. As a result of these measures, Unilife recorded a charge of approximately \$400,000 for severance and related costs during this first fiscal quarter, with an additional charge of approximately \$100,000 expected in the second quarter. The impact of these measures is expected to begin to be reflected during the second quarter of fiscal 2016, and become more meaningful during the second half of fiscal 2016.

Existing Customer Programs and Agreements

Unilife continues to execute according to the program schedules of various customers.

Wearable Injectors

Earlier this month, Unilife announced the signing of the first supply agreement under its November 2013 Master Development and Supply Agreement ("MDSA") with MedImmune, the global biologics research and development arm of AstraZeneca. This supply agreement, executed on October 30, 2015, provides commercial terms, including minimum purchase volumes and unit pricing, for the long-term supply of a customized device from Unilife's Precision-Therapy™ platform of wearable injectors for a monoclonal antibody in late-stage clinical studies in MedImmune's pipeline.

The customization phase of the lead wearable injector program for MedImmune is now nearing completion, and device production has begun at Unilife. Additionally, Unilife is shipping wearable injectors to MedImmune this quarter. In addition to development and material fees already paid by MedImmune, Unilife will begin generating revenue from the sale of these devices in the current quarter of this fiscal year.

In addition to other ongoing customer programs, Unilife expanded its market opportunity in the wearable injector segment with the provision of a 1mL device variant designed to be preferable to disposable auto injectors across factors including patient comfort, reduced pain sensation, connectivity, drug warming and discretion.

Prefilled Syringes

Customer programs for the use of various Unilife products from the Unifill® platform of prefilled syringes continue to move forward. Device batches shipped to customers previously are being used for activities including drug stability studies and fill-finish integration. Additional manufacturing lines are scheduled to be installed over the coming months to further support the commercial rollout schedules of customers. Anticipated annual unit volume requirements for one strategic customer between calendar year 2015 and 2020 have increased significantly per year compared to original estimates.

Other Device Segments

Unilife also advanced various active programs with a number of pharmaceutical customers relating to products from device segments including ocular delivery systems, novel delivery systems and auto injectors during the fiscal quarter.

This quarter, Unilife delivered to a global biopharmaceutical customer customized electronic reusable auto injectors based on the LISA™ device platform on schedule for use in human factors studies. Unilife will recognize \$1.2 million in revenue in the second quarter of fiscal 2016 from the customer for completion of the LISA™ feasibility program in addition to payments received for earlier achieved milestones under the program. The exclusivity period for the LISA™ device platform granted by Unilife under the definitive global strategic agreement signed with the customer on January 15, 2015 commences with Unilife's completion of the deliverables under the feasibility program. The milestones tied to the exclusive period for the Unifill Finesse™ prefilled syringe have also been successfully completed. The parties are also working on agreements for other drug delivery systems, and the relationship between Unilife and the customer continues to be strong.

During September 2015, Unilife announced an amendment to a clinical supply agreement originally signed with Novartis in December 2013 to supply clinical products from one of its platforms of injectable drug delivery systems for use with one of Novartis' targeted early-stage pipeline drugs. Under this amendment to the agreement, Unilife will supply Novartis with additional batches of its customized delivery device to enable administration of a novel investigational Novartis drug into a targeted organ during an ongoing clinical drug trial. Unilife has granted Novartis an option for exclusivity under this agreement.

Commercial Development Pipeline

In addition to existing programs, Unilife continues to negotiate with various other pharmaceutical companies who are seeking access to products from across its portfolio of injectable drug delivery systems. More than a dozen pre-commercial engagements with customers are currently at various stages of negotiations, including several supply agreements with existing and prospective customers. Unilife may receive additional payments from customers, including in some cases exclusivity or access fees, if any of these agreements are finalized and executed.

Financial Results for the First Quarter of Fiscal Year 2016

Revenue for the first quarter of fiscal year 2016 was \$3.2 million, compared to \$1.4 million in the same period last year. Cash receipts from customers for the first quarter of fiscal 2016 was approximately \$2.3 million, compared to \$0.9 million in the same period as last year. Research and development expense for the first quarter of fiscal year 2016 was \$14.6 million, excluding share-based compensation expense, compared to \$10.4 million for the same period in the prior year. Selling, general and administrative expense for the first quarter of fiscal year 2016 was \$7.0 million, excluding share-based compensation expense, compared to \$6.9 million for the same period in the prior year.

The Company's net loss for the first fiscal quarter of 2016 was \$25.9 million, or \$0.21 per share, compared to a net loss of \$22.3 million, or \$0.21 per share, for the same period in the prior year. Adjusted net loss for the first fiscal quarter of 2016 was \$18.5 million, or \$0.15 per share, compared to \$15.9 million or \$0.15 per share for same period in the prior year. Adjusted net loss is a non-GAAP measure that excludes non-cash share-based compensation expense, depreciation and amortization, interest expense and the change in fair value of financial instruments. Please see "Non-GAAP Financial Measures" and "Reconciliation of Non-GAAP Financial Measure," below.

Unilife had \$7.9 million in total cash and cash equivalents, including restricted cash of \$2.1 million, as of September 30, 2015.

Conference Call Information

Management has scheduled a conference call for 4:30 p.m. EST on Monday, November 9, 2015 (Tuesday, November 10, 2015 at 8:30 a.m. AEDT), to review the Company's financial results, commercial partnerships, and future outlook. The conference call and accompanying slide presentation will be broadcast over the Internet as a "live" listen-only Webcast. An archive of the presentation and webcast will be available for 30 days after the call. To listen, please go to: <http://ir.unilife.com/events.cfm>.

About Unilife Corporation

Unilife Corporation (NASDAQ:UNIS / ASX: UNS) is a U.S. based developer and commercial supplier of injectable drug delivery systems. Unilife's broad portfolio of proprietary technologies includes prefilled syringes with automatic needle retraction, drug reconstitution delivery systems, auto-injectors, wearable injectors, insulin patch pumps, ocular delivery systems and novel systems. Each of these innovative and highly differentiated platforms can be customized to address specific customer, drug and patient requirements. Unilife's global headquarters and state-of-the-art manufacturing facilities are located in York, PA. For more information, please visit www.unilife.com or download the Unilife IRapp on your [iPhone](#), [iPad](#) or [Android device](#).

Forward-Looking Statements

This press release contains forward-looking statements. All statements that address operating results, performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including, but not limited to, expectations regarding reductions to the Company's selling, general and administrative expenses and its research and development expenses, estimates of employee headcount reductions, expenditures that may be incurred by the Company in connection with the reduction in force, expectations regarding cash receipts from customers or potential strategic transactions. 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" and elsewhere in our Annual Report on Form 10-K, those described from time to time in other reports which we file with the Securities and Exchange Commission, and the following additional risks: that OrbiMed may, as permitted under the amended Credit Agreement with OrbiMed, exercise its discretion not to make additional loans to the Company; that we may not be successful in raising additional capital; that we may not be able to enter into or receive sufficient cash from customer agreements; that we may not be able to enter into or complete any strategic transaction in the stated timeframe or at all or that any such transaction will enhance stockholder value; that we may not be able to implement the reduction in force in various jurisdictions as planned; possible changes in the size and components of the expected costs and charges associated with the reduction in force; risks associated with the Company's ability to achieve the benefits of the reduction in force; and completion of quarter-end financial reporting processes and review.

Non-GAAP Financial Measures

U.S. securities laws require that when we publish any non-GAAP financial measure, we disclose the reason for using the non-GAAP measure and provide reconciliation to the most directly comparable GAAP measure. The presentation of research and development expense excluding share-based compensation expense, selling, general and administrative expense excluding share-based compensation expense, adjusted net income (loss) and adjusted net income (loss) per share are non-GAAP measures. Adjusted net income (loss) represents net income (loss) calculated in accordance with U.S. GAAP as adjusted for the impact of share-based compensation expense, depreciation and amortization, change in fair value of financial instruments and interest expense.

Management believes the presentation of research and development expense excluding share-based compensation expense, selling, general and administrative expense excluding share-based compensation expense, adjusted net income (loss) and adjusted net income (loss) per share provides useful information because these measures enhance its own evaluation, as well as investor's understanding, of the Company's core operating and financial results. Non-GAAP financial measures should be considered in addition to results prepared in accordance with GAAP, but should not be considered a substitute for, or superior

to, GAAP results. A reconciliation of net income (loss) to adjusted net income (loss) is included in the attached table.

UNIS-G

Investor Contacts (US):	Analyst Inquiries	Investor Contacts (Australia)
Todd Fromer / Garth Russell	Lynn Pieper	Jeff Carter
KCSA Strategic Communications	Westwicke Partners	Unilife Corporation
P: + 1 212-682-6300	P: + 1 415-202-5678	P: + 61 2 8346 6500

UNILIFE CORPORATION AND SUBSIDIARIES
Consolidated Balance Sheets
(unaudited)

	<u>September 30, 2015</u>	<u>June 30, 2015</u>
	(in thousands, except share data)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 5,801	\$ 12,303
Restricted cash	2,092	2,400
Accounts receivable	1,413	1,530
Inventories	107	151
Prepaid expenses and other current assets	1,206	656
Total current assets	<u>10,619</u>	<u>17,040</u>
Property, plant and equipment, net	79,126	66,148
Goodwill	8,857	9,685
Other assets	1,205	1,256
Total assets	<u>\$ 99,807</u>	<u>\$ 94,129</u>
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	\$ 9,090	\$ 4,042
Accrued expenses	19,087	5,074
Current portion of long-term debt	1,243	775
Deferred revenue	3,910	4,942
Total current liabilities	<u>33,330</u>	<u>14,833</u>
Long-term debt, less current portion	80,595	79,660
Deferred revenue	17,550	17,550
Total liabilities	<u>131,475</u>	<u>112,043</u>
Stockholders' Deficit:		
Preferred stock, \$0.01 par value, 50,000,000 shares authorized as of September 30, 2015; none issued or outstanding as of September 30, 2015 and June 30, 2015	--	--
Common stock, \$0.01 par value, 250,000,000 shares authorized as of September 30, 2015; 139,138,898 and 131,976,153 shares issued, and 139,110,228 and 131,947,483 shares outstanding as of September 30, 2015 and June 30, 2015, respectively	1,391	1,320
Additional paid-in-capital	377,672	364,817
Accumulated deficit	(410,444)	(384,580)
Accumulated other comprehensive (loss) income	(147)	669
Treasury stock, at cost, 28,670 shares as of September 30, 2015 and June 30, 2015	(140)	(140)
Total stockholders' deficit	<u>(31,668)</u>	<u>(17,914)</u>
Total liabilities and stockholders' deficit	<u>\$ 99,807</u>	<u>\$ 94,129</u>

(unaudited)

	Three Months Ended September 30,	
	2015	2014
	(in thousands, except share data)	
Revenue	\$ 3,187	\$ 1,380
Research and development	16,004	10,976
Selling, general and administrative	9,228	8,200
Depreciation and amortization	1,543	1,100
Total operating expenses	26,775	20,276
Operating loss	(23,588)	(18,896)
Interest expense	1,684	1,109
Change in fair value of financial instruments	602	2,230
Other (income) expense, net	(10)	27
Net loss	\$ (25,864)	\$ (22,262)
Net loss per share:		
Basic and diluted net loss per share	\$ (0.21)	\$ (0.21)

UNILIFE CORPORATION AND SUBSIDIARIES
Reconciliation of Non-GAAP Measure
(unaudited)

	Three Months Ended September 30,	
	2015	2014
	(in thousands, except per share data)	
Net loss	\$ (25,864)	\$ (22,262)
Share-based compensation expense	3,584	1,888
Depreciation and amortization	1,543	1,100
Interest expense	1,684	1,109
Change in fair value of financial instruments	602	2,230
Adjusted net loss	\$ (18,451)	\$ (15,935)
Adjusted net loss per share - diluted	\$ (0.15)	\$ (0.15)

	Three Months Ended September 30,	
	2015	2014
	(in thousands)	
Research and development expense	\$ 16,004	\$ 10,976
Share-based compensation expense	(1,362)	(607)
Adjusted research and development expense	\$ 14,642	\$ 10,369

	Three Months Ended September 30,	
	2015	2014
	(in thousands)	
Selling, general and administrative expense	\$ 9,228	\$ 8,200
Share-based compensation expense	(2,222)	(1,281)
Adjusted selling, general and administrative expense	\$ 7,006	\$ 6,919

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/unilife-corporation-announces-financial-results-for-the-first-quarter-of-fiscal-year-2016-300174703.html>

SOURCE Unilife Corporation

News Provided by Acquire Media