Unilife Corporation Announces Financial Results For the Fourth Quarter and Full Fiscal Year 2015

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Significant cost reduction and business realignment initiative implemented

York, PA (September 15, 2015) 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 fiscal fourth quarter and full fiscal year ending June 30, 2015.

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. Under a cost reduction and business realignment initiative implemented today, the Company has reduced its workforce by approximately 50 employees, or approximately 17% of its workforce, and the Company will significantly reduce its operating expenses in fiscal 2016.

Compared to the annualized run rate for operating expenses in the fourth quarter of fiscal year 2015, R&D expense in fiscal 2016 is anticipated to decrease by 25% to 30% and SG&A expense by approximately 20%. These comparisons exclude share-based compensation and depreciation expense. As a result of this initiative, we expect to record a charge of approximately $0.4 million for severance and related costs in the first fiscal quarter of 2016.

Mr. Alan Shortall, Chairman and CEO of Unilife, commented: "This cost reduction and realignment will enable us to dedicate resources to support customer ramp schedules under existing supply agreements, and enter into additional strategic relationships that represent attractive opportunities for growth. Active programs and discussions with all previously disclosed strategic customers are moving forward favorably."

"Cash receipts during fiscal 2016 are expected to remain lumpy due to the milestone-based nature of these existing programs, and the timing as to when additional upcoming agreements are formalized. While there is potential to receive upfront or exclusivity fees associated with some of these upcoming agreements, we expect that existing and future customization programs will continue to represent the majority of our cash receipts this fiscal year. Product shipments from device platforms including prefilled syringes and wearable injectors will also gradually increase this fiscal year to support customer timelines for commercial rollout and clinical drug trials, and become more meaningful as programs advance through the start of fiscal 2017 and beyond."

"In addition to cash receipts from existing and prospective customers, we have a number of other options available to manage our cash position, including a previously disclosed equity line and an ATM program. Furthermore, in response to third-party initiated expressions of interest, we have engaged Morgan Stanley to conduct a review of strategic alternatives to maximize shareholder value. This review may result in the acquisition of our Company, a strategic investment with one or more parties, and or the licensing of one or more of our proprietary technologies," Mr. Shortall concluded.

Highlights from the Year

Commercial Development

Unilife's strategy to build long-term, strategic partnerships with pharmaceutical and biotechnology companies continued to gather pace during fiscal year 2015. The Company broadened relationships with multiple existing customers as initial programs accelerated, and preparations for work on additional programs commenced. Discussions with many additional pharmaceutical companies seeking long-term access to Unilife's products and services also advanced favorably.

In October 2014, Unilife announced the signing of a worldwide Master Services and Commercial Supply Agreement with Sanofi to be the sole provider of cartridge-based wearable injectors for all of Sanofi's applicable large dose volume drugs, excluding insulins, for a minimum 15 years. Additionally, the agreement will allow Sanofi to make Unilife's wearable injectors available to Sanofi's partners for use with applicable molecules under joint collaborations.

In December 2014, Unilife announced the signing of a worldwide 10-year Commercial Supply Agreement with a global pharmaceutical company for the use of the Depot-ject™ delivery system with an approved ocular injection therapy. The identity of the pharmaceutical company and its target therapy, which is approved in the U.S and Europe for the treatment of a high prevalence disease of the retina, remain confidential to protect the commercial interests of the customer.

As previously disclosed, on January 15, 2015 Unilife entered into a definitive global strategic agreement with AbbVie Inc. for the customization and supply of its injectable drug delivery systems for use with AbbVie's drug portfolio. Unilife has been selected by AbbVie as a preferred partner for the customization and supply of innovative, differentiated drug delivery systems. AbbVie paid $5 million for the exclusive right to form and enter into a mutually-agreeable development and supply agreement with Unilife to include exclusive access to the Unifill Finesse™ prefilled syringe and the LISA™ reusable auto-injector for target therapies within AbbVie's drug portfolio for the treatment of auto-immune diseases, as well as associated exclusivity fees. The target therapies and conditions for which these systems will be used are confidential under the terms of the agreement.

Manufacturing

Unilife continued to increase the size and scale of its production facilities and operational infrastructure during fiscal year 2015. Multiple manufacturing lines are at various stages of use, assembly, installation and development across multiple device platforms, including prefilled syringes and wearable injectors. Additional assembly lines are scheduled to become operational during fiscal year 2016. Product shipments to customers are scheduled to increase across multiple device segments during fiscal year 2016 to support the commercial rollout timelines of customers.

Product shipments from the Unifill platform are expected to continue to increase year over year and to become more meaningful in 2017 and beyond. In regards to Unilife's portfolio of wearable injectors, the Company successfully filled and qualified its products within standard high-speed biopharmaceutical drug filling operations. Shipments of wearable injectors for use in clinical trials are also scheduled to commence during the first half of fiscal year 2016.

To support the specific scale-up requirements of its customers, Unilife also commenced activities to double the size of its cleanroom space and expand the overall building footprint at its York, PA facility to accommodate additional manufacturing lines and production infrastructure.

Product Platforms

During fiscal year 2015, Unilife attained what it considers to be a critical mass of platform-based device technologies that can together accommodate virtually all types of injectable biologics, drugs and vaccines identified by the Company as attractive commercial opportunities for the generation of long-term supply agreements.

For previously disclosed device segments such as wearable injectors, prefilled syringes, smart reusable auto injectors and ocular delivery systems, the Company expanded its portfolio of product configurations and customization options available to pharmaceutical companies. This included the development of systems to permit data connectivity via Bluetooth LE and other wireless systems, that can be integrated within applicable products for use with smartphone apps to provide features such as patient reminders, status updates and data informatics.

In July 2015, Unilife announced the development of the Imperium™ platform of instant patch pumps for insulin. Imperium is a prefilled, disposable, multi-day wearable insulin pump that does not require filling or assembly by the patient and that is customizable to meet the specific needs of insulin providers, insulin therapies, and patients. Because it is prefilled and pre-assembled like an insulin pen, only three intuitive steps are required to commence continuous subcutaneous insulin infusion, with on-demand bolus delivery available to the user via the simple push of a button. Unilife is in discussions with a number of diabetes industry leaders regarding the potential long-term commercial supply of Imperium with specific brands of insulin.

Financial Results for the Full Fiscal Year and Fourth Quarter of 2015

Revenue for the fourth quarter of fiscal year 2015 and for the fiscal year 2015 was $3.5 million and $13.2 million, respectively. This compares to revenue in the fourth quarter of the fiscal year 2014 and for the fiscal year 2014 of $6.5 million and $14.7 million, respectively. Cash receipts from customers for the fiscal year 2015 was $22.7 million compared to cash receipts from customers of $23.7 million for the fiscal year 2014. Deferred revenue increased to $22.5 million as of June 30, 2015, up from $13.3 million on June 30, 2014.

Research and development expense for the fourth quarter of fiscal year 2015 and for the fiscal year 2015 was $15.5 million and $48.7 million, respectively, excluding share-based compensation and depreciation expense. This compares to research and development expense in the fourth quarter of the fiscal year 2014 and for the fiscal year 2014 of $11.3 million and $31.0 million, respectively, excluding share-based compensation expense and depreciation expense.

Selling, general and administrative expense for the fourth quarter of fiscal year 2015 and for the fiscal year 2015 was $7.0 million and $28.1 million, respectively, excluding share-based compensation and depreciation expense. This compares to selling, general and administrative expense in the fourth quarter of the fiscal year 2014 and for the fiscal year 2014 of $7.2 million and $22.7 million, respectively excluding share-based compensation expense and depreciation expense.

The Company's net loss for the fiscal year of 2015 was $90.8 million, or $0.81 per share, compared to a net loss of $57.9 million, or $0.59 per share, for fiscal year 2014.

Adjusted net loss for the full fiscal year of 2015 was $63.5 million, or $0.57 per share, compared to $38.8 million or $0.40 per share for the prior year. Adjusted net loss excludes non-cash share-based compensation expense, depreciation and amortization, interest expense and the change in fair value of financial instruments.

Unilife had $14.7 million in total cash and cash equivalents, including restricted cash of $2.4 million, as of June 30, 2015.

Conference Call Information

Management has scheduled a conference call for 4:30 p.m. U.S. EDT on Monday, September 14, 2015 (Tuesday, September 15, 2015, at 6:30 a.m. AEST), to review the Company's financial results, customer 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 performance, events or developments that we expect or anticipate will occur in the future are 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" and elsewhere 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.

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.

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Investor Contacts (US):	***Analyst Enquiries***	***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)

	June 30, 2015	2014
	(in thousands, except share data)	
Assets		
Current Assets:		
Cash and cash equivalents	$ 12,303	$ 8,368
Restricted cash	2,400	2,400
Accounts receivable	1,530	1,860
Inventories	151	142
Prepaid expenses and other current assets	656	1,108
Total current assets	17,040	13,878
Property, plant and equipment, net	66,148	54,588
Goodwill	9,685	11,830
Other assets	1,256	1,472
Total assets	$ 94,129	$ 81,768
Liabilities and Stockholders' (Deficit) Equity		
Current Liabilities:		
Accounts payable	$ 4,042	$ 3,583
Accrued expenses	5,074	3,339
Current portion of long-term debt	775	613
Deferred revenue	4,942	717
Total current liabilities	14,833	8,252
Long-term debt, less current portion	79,660	54,835
Deferred revenue	17,550	12,550
Total liabilities	112,043	75,637
Stockholders' (Deficit) Equity:		
Preferred stock, $0.01 par value, 50,000,000 shares authorized as of June 30, 2015; none issued or outstanding as of June 30, 2015 and 2014	—	—
Common stock, $0.01 par value, 250,000,000 shares authorized as of June 30, 2015; 131,976,153 and 103,617,278 shares issued, and 131,947,483 and 103,588,608 shares outstanding as of June 30, 2015 and 2014, respectively	1,320	1,036
Additional paid-in-capital	364,817	296,169
Accumulated deficit	(384,580)	(293,731)
Accumulated other comprehensive income	669	2,797
Treasury stock, at cost, 28,670 shares as of June 30, 2015 and 2014	(140)	(140)
Total stockholders' (deficit) equity	(17,914)	6,131
Total liabilities and stockholders' (deficit) equity	$ 94,129	$ 81,768

UNILIFE CORPORATION AND SUBSIDIARIES
Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Year Ended June 30,	
	2015	2014	2015	2014
	(in thousands, except per share data)			
Revenue	$ 3,454	$ 6,546	$ 13,158	$ 14,689
Operating expenses:				
Research and development	16,989	11,887	52,487	34,111
Selling, general and administrative	9,413	8,022	36,176	27,894
Depreciation and amortization	1,386	1,011	4,923	4,079
Total operating expenses	27,788	20,920	93,586	66,084
Operating loss	(24,334)	(14,374)	(80,428)	(51,395)
Interest expense	1,658	1,692	6,368	7,332
Other income	(223)	(203)	(226)	(228)
Change in fair value of financial instruments	326	(600)	4,279	(600)
Net loss	$ (26,095)	$ (15,263)	$ (90,849)	$ (57,899)
Net loss per share:				
Basic and diluted net loss per share	$ (0.22)	$ (0.15)	$ (0.81)	$ (0.59)

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

	Three Months Ended June 30,		Year Ended June 30,	
	2015	2014	2015	2014
	(in thousands, except per share data)			
Net loss	$ (26,095)	$ (15,263)	$ (90,849)	$ (57,899)
Share-based compensation expense	3,970	1,441	11,775	8,316
Depreciation and amortization	1,386	1,011	4,923	4,079
Interest expense	1,658	1,692	6,368	7,332
Change in fair value of financial instruments	326	(600)	4,279	(600)
Adjusted net loss	$ (18,755)	$ (11,719)	$ (63,504)	$ (38,772)
Adjusted net loss per share – diluted	$ (0.16)	$ (0.12)	$ (0.57)	$ (0.40)

	Three Months Ended June 30,		Year Ended June 30,	
	2015	2014	2015	2014
	(in thousands)			
Research and development expense	$ 16,989	$ 11,887	$ 52,487	$ 34,111
Share-based compensation expense	(1,533)	(630)	(3,747)	(3,077)
Adjusted research and development expense	$ 15,456	$ 11,257	$ 48,740	$ 31,034

	Three Months Ended June 30,		Year Ended June 30,	
	2015	2014	2015	2014
	(in thousands)			
Selling, general and administrative expense	$ 9,413	$ 8,022	$ 36,176	$ 27,894
Share-based compensation expense	(2,437)	(811)	(8,028)	(5,239)
Adjusted selling, general and administrative expense	$ 6,976	$ 7,211	$ 28,148	$ 22,655