

UNILIFE CORP

FORM 8-K (Current report filing)

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Address	250 CROSS FARM LANE YORK, PA 17406
Telephone	(717) 384-3400
CIK	0001476170
Symbol	UNIS
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	06/30

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

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

Date of Report (Date of earliest event reported): February 9, 2016 (February 9, 2016)

UNILIFE CORPORATION

(Exact name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-34540
(Commission
File Number)

27-1049354
(IRS Employer
Identification No.)

250 Cross Farm Lane, York, Pennsylvania
(Address of Principal Executive Offices)

17406
(Zip Code)

Registrant's telephone number, including area code: (717) 384-3400

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition

On February 9, 2016, Unilife Corporation (“Unilife”) issued a press release announcing the financial results for the six months ended December 31, 2015. A copy of the press release is attached hereto as Exhibit 99.1.

On February 9, 2016, Unilife filed its Appendix 4D (“Half Year Report”) for the six months ended December 31, 2015 with the Australian Securities Exchange (“ASX”), a copy of which is attached hereto as Exhibit 99.2. The Half Year Report is prepared in U.S. dollars pursuant to accounting principles generally accepted in the United States of America and otherwise in compliance with the requirements of Australian law and the ASX listing rules.

The information hereunder shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference into a filing under the Securities Act of 1933, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure

See Item 2.02 above.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated February 9, 2016.

99.2 Appendix 4D lodged with the Australian Securities Exchange on February 9, 2016.

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 hereunto duly authorized.

Unilife Corporation

Date: February 9, 2016

By: _____ /s/ Alan Shortall

Alan Shortall
Chairman and Chief Executive Officer

EXHIBIT INDEX

EXHIBIT
NUMBER

DESCRIPTION

99.1	Press release dated February 9, 2016.
99.2	Appendix 4D lodged with the Australian Securities Exchange on February 9, 2016.



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

York, PA (February 9, 2016) — 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 second quarter of fiscal 2016 (three months ended December 31, 2015).

Financial Results for the Second Quarter of Fiscal 2016

Revenue for the second quarter of fiscal 2016 was \$4.5 million, compared to \$5.4 million in the same period last year. Cash receipts from customers for the second quarter of fiscal 2016 were \$17.8 million, compared to \$7.3 million in the same period last year. Research and development (R&D) expense for the second quarter of fiscal 2016 was \$10.5 million, compared to \$11.3 million in the same period last year. Selling, general, and administrative (SG&A) expense for the second quarter of fiscal 2016 was \$8.8 million, compared to \$9.5 million in the same period last year. Adjusted R&D expense for the second quarter of fiscal 2016 was \$9.4 million, compared to \$10.7 million in the same period last year. Adjusted SG&A expense for the second quarter of fiscal 2016 was \$6.5 million, compared to \$7.3 million in the same period last year. These comparisons exclude share-based compensation.

The Company’s net loss for the second quarter of fiscal 2016 was \$25.4 million, or \$0.20 per share, compared to a net loss of \$19.4 million, or \$0.18 per share, for the same period last year. Adjusted net loss for the second fiscal quarter of 2016 was \$11.4 million, or \$0.09 per share, compared to \$12.5 million or \$0.12 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 \$20.4 million in total cash and cash equivalents, including restricted cash of \$2.4 million, as of December 31, 2015.

Impact of Previously Announced Cost Reduction and Business Realignment Initiative on Adjusted Research and Development Expense and Adjusted Selling, General and Administrative Expense

In parallel with the ongoing Strategic Review process and execution to existing customer programs, the Company continues to implement previously announced cost reduction and business realignment initiatives. As a result of these initiatives, the Company’s adjusted R&D expense decreased by 36% from approximately \$14.6 million in the first quarter of fiscal 2016 (three months ended September 30, 2015) to approximately \$9.4 million in the second quarter of fiscal 2016. Adjusted SG&A expense decreased by 7% from approximately \$7.0 million in the first quarter of fiscal 2016 to approximately \$6.5 million in the second quarter of fiscal 2016. These comparisons exclude share-based compensation and depreciation expense.

Projected Reduction in Full Year Operating Expenses for Fiscal 2016

The Company still expects up to a 30% decrease in adjusted R&D expense for fiscal 2016 when compared to the annualized run rate in the fourth quarter of fiscal 2015, which was approximately \$61.8 million. The Company now expects adjusted SG&A expense for fiscal 2016 to decrease between 5% and 10% percent when

compared to the annualized run rate in the fourth quarter of fiscal 2015, which was approximately \$27.9 million, due to higher legal and professional expenses, partially offset by lower personnel expenses. These comparisons exclude share-based compensation and depreciation expense.

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, and 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 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 the Company may not achieve the benefits of the reduction in force; that our cost reduction and business realignment initiative may adversely impact our ability to continue to operate the business; that we may not be able to finalize terms, or ultimately enter into definitive agreements with respect to a transaction in connection with the Strategic Review or pursue any other alternative; 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. Adjusted research and development expenses and adjusted selling, general and administrative expense represent research and development expense and selling, general and administrative expense, respectively, calculated in accordance with U.S. GAAP as adjusted for the impact of share-based compensation and depreciation 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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UNILIFE CORPORATION AND SUBSIDIARIES
Consolidated Balance Sheets
(unaudited)

	December 31, 2015	June 30, 2015
	(in thousands, except share data)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 17,971	\$ 12,303
Restricted cash	2,400	2,400
Accounts receivable	2,957	1,530
Inventories	122	151
Prepaid expenses and other current assets	2,481	656
Total current assets	25,931	17,040
Property, plant and equipment, net	81,761	66,148
Goodwill	9,249	9,685
Other assets	1,296	1,256
Total assets	<u>\$ 118,237</u>	<u>\$ 94,129</u>
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	\$ 10,663	\$ 4,042
Accrued expenses	18,142	5,074
Current portion of long-term debt	1,949	775
Preferred stock conversion liability	4,802	—
Deferred revenue	3,715	4,942
Total current liabilities	39,271	14,833
Long-term debt, less current portion	93,189	79,660
Deferred revenue	32,550	17,550
Total liabilities	165,010	112,043
Redeemable convertible preferred stock, Series A – Subject to redemption, \$0.01 par value, 790 shares authorized, 790 and 0 shares issued, and 490 and 0 shares outstanding as of December 31, 2015 and June 30, 2015, respectively	2,450	—
Stockholders' Deficit:		
Preferred stock, \$0.01 par value, 50,000,000 shares authorized as of December 31 2015; none issued or outstanding as of December 31, 2015 and June 30, 2015	—	—
Common stock, \$0.01 par value, 350,000,000 shares authorized as of December 31, 2015; 155,438,426 and 131,976,153 shares issued, and 155,409,756 and 131,947,483 shares outstanding as of December 31, 2015 and June 30, 2015, respectively	1,554	1,320
Additional paid-in-capital	384,999	364,817
Accumulated deficit	(435,867)	(384,580)
Accumulated other comprehensive income	231	669
Treasury stock, at cost, 28,670 shares as of December 31, 2015 and June 30, 2015	(140)	(140)
Total stockholders' deficit	(49,223)	(17,914)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	<u>\$ 118,237</u>	<u>\$ 94,129</u>

UNILIFE CORPORATION AND SUBSIDIARIES
Consolidated Statements of Operations
(unaudited)

	<u>Three Months Ended</u> <u>December 31,</u>		<u>Six Months Ended</u> <u>December 31,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
	(in thousands, except per share data)			
Revenue	\$ 4,499	\$ 5,403	\$ 7,686	\$ 6,783
Research and development	10,533	11,309	26,537	22,285
Selling, general and administrative	8,774	9,508	18,002	17,708
Depreciation and amortization	1,422	1,253	2,965	2,353
Total operating expenses	<u>20,729</u>	<u>22,070</u>	<u>47,504</u>	<u>42,346</u>
Operating loss	(16,230)	(16,667)	(39,818)	(35,563)
Interest expense	1,872	1,805	3,556	2,914
Change in fair value of financial instruments	7,325	940	7,927	3,170
Other (income) expense, net	(4)	(25)	(14)	2
Net loss	<u>\$ (25,423)</u>	<u>\$ (19,387)</u>	<u>\$ (51,287)</u>	<u>\$ (41,649)</u>
Net loss per share:				
Basic and diluted net loss per share	<u>\$ (0.20)</u>	<u>\$ (0.18)</u>	<u>\$ (0.41)</u>	<u>\$ (0.39)</u>

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2015	2014	2015	2014
	(in thousands, except per share data)			
Net loss	\$(25,423)	\$(19,387)	\$(51,287)	\$(41,649)
Share-based compensation expense	3,436	2,840	7,020	4,728
Depreciation and amortization	1,422	1,253	2,965	2,353
Interest expense	1,872	1,805	3,556	2,914
Change in fair value of financial instruments	7,325	940	7,927	3,170
Adjusted net loss	<u>\$(11,368)</u>	<u>\$(12,549)</u>	<u>\$(29,819)</u>	<u>\$(28,484)</u>
Adjusted net loss per share—diluted	<u>\$ (0.09)</u>	<u>\$ (0.12)</u>	<u>\$ (0.24)</u>	<u>\$ (0.27)</u>

	Three Months Ended December 31,		Six Months Ended December 31,	
	2015	2014	2015	2014
	(in thousands, except per share data)			
Research and development expense	\$ 10,533	\$ 11,309	\$ 26,537	\$ 22,285
Share-based compensation expense	(1,165)	(584)	(2,527)	(1,191)
Adjusted research and development expense	<u>\$ 9,368</u>	<u>\$ 10,725</u>	<u>\$ 24,010</u>	<u>\$ 21,094</u>

	Three Months Ended December 31,		Six Months Ended December 31,	
	2015	2014	2015	2014
	(in thousands, except per share data)			
Selling, general and administrative expense	\$ 8,774	\$ 9,508	\$ 18,002	\$ 17,708
Share-based compensation expense	(2,271)	(2,256)	(4,493)	(3,537)
Adjusted selling, general and administrative expense	<u>\$ 6,503</u>	<u>\$ 7,252</u>	<u>\$ 13,509</u>	<u>\$ 14,171</u>



UNILIFE CORPORATION

ARBN 141 042 757

**Appendix 4D – Half Year Report
Six months ended 31 December 2015**

Results for announcement to the market

UNILIFE CORPORATION HIGHLIGHTS

Results for Announcement to the Market

				<u>Six Months Ended 31 December 2015 US\$000's</u>	<u>Six Months Ended 31 December 2014 US\$000's</u>
Revenues from ordinary activities	Up	13.3%	to	7,686	6,783
Profit (loss) from ordinary activities after tax attributable to members	Up	23.1%	to	(51,287)	(41,649)
Net profit (loss) for the period attributable to members	Up	23.1%	to	(51,287)	(41,649)

<u>Common Stock/CDI Dividends (distribution)</u>	<u>Amount per security</u>	<u>Franked amount per security</u>
Final dividend	N/A	N/A
Interim dividend	N/A	N/A
Total	N/A	N/A
Record date for determining entitlements to the dividend		N/A

Results of Operations

Revenues increased from US\$6.8 million during the six months ended 31 December 2014 to US\$7.7 million during the six months ended 31 December 2015. This increase was primarily attributable to additional revenue related to development activities for various customers.

Net loss increased from US\$41.6 million during the six months ended 31 December 2014 to US\$51.3 million during the six months ended 31 December 2015. The increase in net loss is primarily attributable to an increase in research and development cost and the change in fair value of financial instruments.

Basis of the Preparation of the Half Year Report

The half year report has been prepared in accordance with ASX Listing Rule 4.2A.3 and the disclosure requirements of ASX Appendix 4D.

The half year report has been prepared in accordance with accounting principles generally accepted in the United States of America.

The Board of Directors does not recommend that a dividend on Common Stock/CDI relating to the six months ended 31 December 2015 be paid. As such, there is no applicable record date.

Net Tangible Assets per Security

	<u>31 December 2015</u>	<u>31 December 2014</u>
Net tangible assets per share	US(\$0.38)	US(\$0.26)
Net tangible assets per CDI	A(\$0.06)	A(\$0.04)

ALAN SHORTALL
Chairman and Chief Executive Officer

Date: 10 February 2016

Half Year Report to 31 December 2015
Unilife Corporation ARBN 141 042 757