

UNILIFE CORP

FORM 8-K (Current report filing)

Filed 11/17/16 for the Period Ending 11/17/16

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 & Distribution
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): November 17, 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 7.01. Regulation FD Disclosure.

On November 17, 2016, Unilife Corporation (the “Company”) posted to the Investors link at www.unilife.com an investor presentation attached to this report as Exhibit 99.1 (the “Investor Presentation”). The Company intends to use the Investor Presentation at the Jefferies Global Healthcare Conference at 4:40 p.m. GMT (11:40 a.m. EST) on November 17, 2016.

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 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Unilife Corporation Investor Presentation.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

Unilife Corporation

Date: November 17, 2016

By: /s/ John Ryan

Name: John Ryan

Title: President and Chief Executive Officer



Industry-Leading Wearable Injectors, People and Partners

November 17, 2016



Forward Looking Statements

This presentation 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 filed with the U.S. Securities and Exchange Commission ("SEC") on October 24, 2016, those described from time to time in other reports which we file with the SEC, and other risks and uncertainties including, without limitation: that Amgen may not purchase the remaining \$5 million balance of the senior secured convertible note in January 2017 or the additional \$10 million senior secured convertible note in January 2018; and that the Company's focus on wearable injector programs with key pharmaceutical customers may not be successful and / or result in the commercialization and sale of the Company's products.



Industry-Leading Wearable Injectors, People and Partners



An Attractive, Growing and Under-Served Market

- Wearable injectors to deliver biologics
- Large biopharma seek platform-based systems for use with multiple target drugs
- Platforms support effective lifecycle management of multiple target therapies

The Industry's Best Wearable Injector Portfolio

- The first pre-filled, pre-assembled wearable injector portfolio
- Fully integrated, ready-to-inject therapies
- Customers can expect unique therapy brand identity via wearable platform use

The Right People and Partners for Commercial Success

- Focused on programs and path to sales
- Rigorous cost controls, reduced cash burn
- Strategic collaboration with Amgen
- Strong partnership with OrbiMed
- Established base of customers, programs

Strong, Disciplined Team with Deep Industry and Business Experience



John Ryan
President and CEO



David Hastings
SVP and CFO



Ian Hanson
SVP and COO



Michael Ratigan
*SVP, Chief
Commercial Officer*



Stephanie Walters
*SVP, GC and
Secretary*



Rick Bente
*VP, Combination
Products*



Molly Weaver, PhD
*VP Quality &
Regulatory Affairs*

Strengthened Board with Substantial Life Sciences Experience



Mary Kate Wold,
Chair



Rosemary Crane



Duane DeSisto



Harry Hamill



Mike Kamarck, PhD

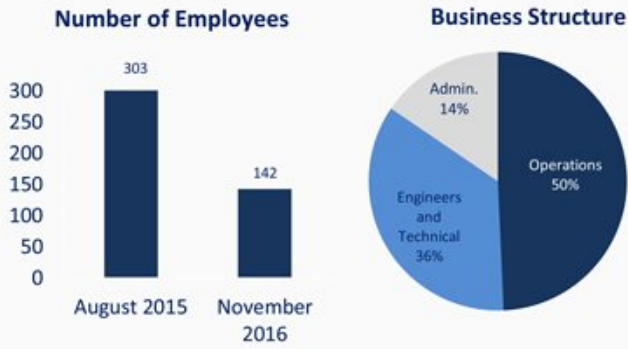


John Lund



Jeff Carter

Realigned for Disciplined Execution, Reduced R&D and SG&A Expense



* Includes share based compensation expense of \$4.0 M, \$3.6M, \$3.4M, \$5.5M, \$1.3M and \$1.0M respectively.

[^] Q3 2016 SG&A includes \$2.2M charge for severance related expense relating to the departure of the former CEO and COO, and a \$5.0M charge relating to the strategic review process.

- Company aligned to focus on wearable programs
- Workforce reduced ↓53%, 86% in product-focused roles
- Teams aligned for optimal performance on customer programs
- Focused on innovating to maintain wearable injector leadership position

- Disciplined team rigorously implementing strategy
- Reduction in R&D and SG&A expense and capital expenditures
- Reductions not expected to detract in any way from wearable injector focus



Strategic Partners and Customers



- Leading healthcare-focused global investment firm with approximately \$14 billion in assets under management
- \$70 million in debt financing provided since 2014



- Global strategic collaboration signed February 2016
- \$75M provided to date with \$5M convertible note contemplated in Jan. 2017 and \$10M in Jan. 2018
- Exclusive and non-exclusive access within defined areas
- Development programs underway



- Long-term development and supply agreement signed 2013
- Commercial supply agreement with minimum volumes for lead molecule signed in 2015



- Agreement signed in 2014 for Unilife to be exclusive supplier for all Sanofi (non-cartridge) wearable drugs
- Minimum 15 year term
- Extends to drug collaboration partners



Improving Patient Experience to Optimize Therapy Compliance



Reducing Injection Frequency

E.g. 1mL every two weeks
to 2mL every month



Reducing Injections Per Dose

E.g. Three injections per dose
to 1 injection for full dose



Reducing Pain and Discomfort

E.g. 180mg (1mL) in 10 sec.
to 180mg (2mL) in 45 sec.



Ease of Use

Intuitive steps of use with patient-
focused, fully integrated drug-
device combination products



Improving Mobility

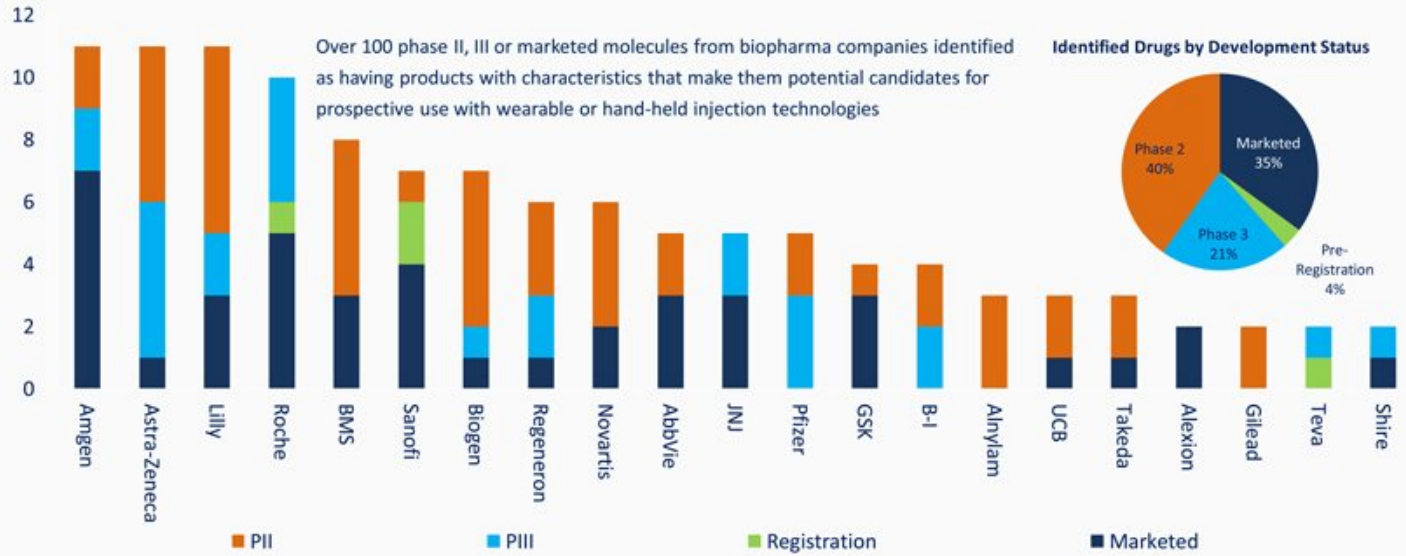
E.g. Shift from IV infusion in specialty
care center to subQ self-injection
wherever the patient is



Enabling Data Connectivity

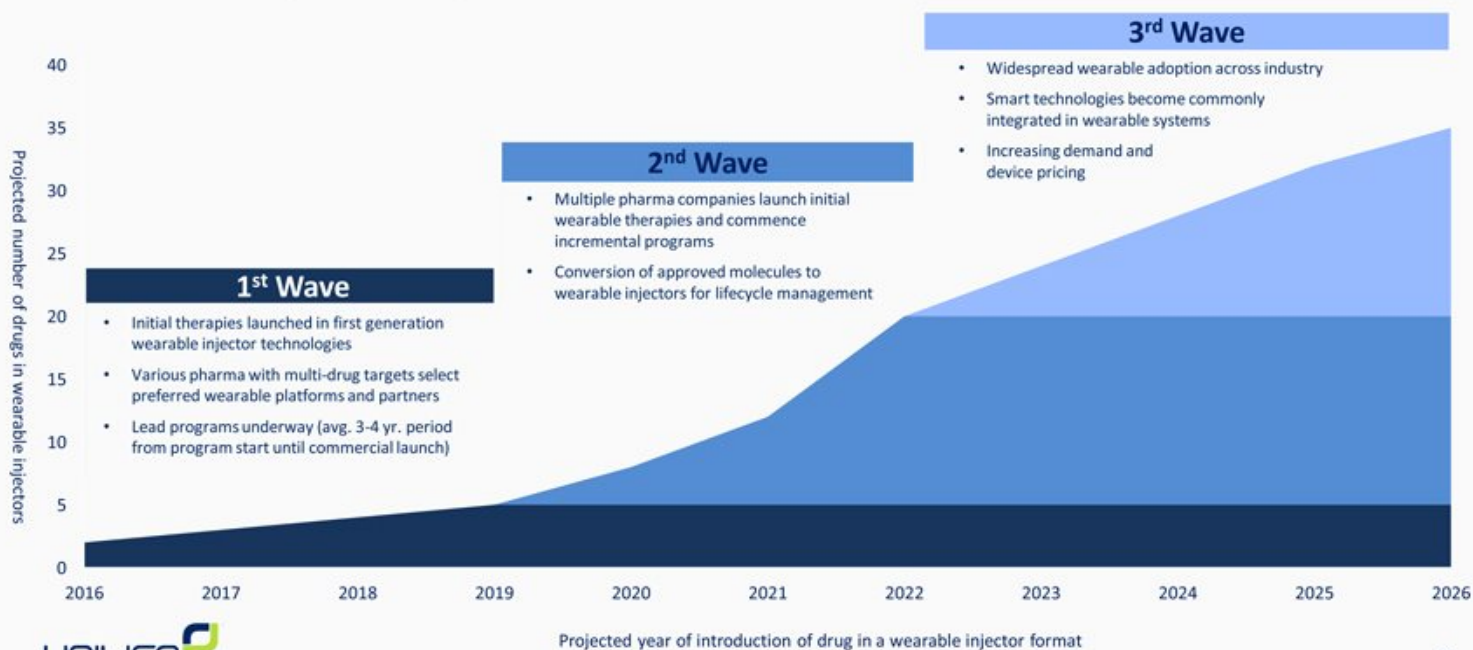
Integration of device, drug
and data within a connected
health ecosystem

BioPharma Companies with Potential for Multiple Wearable Programs



* Suitability based on criteria incl. dose strength, admin. route, injection frequency, drug formulation and potential for patient self-injection. Phase 1 molecules, insulin therapies and biosimilars not included. Based on publicly available information as of October 2016 from sources including clinicaltrials.gov, biopharma company statements and Adis insight.

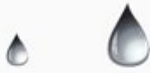
Embraced by Industry, Poised for a Decade of Growth and Consolidation



A Broad, Platform-Based Portfolio for any Wearable Therapy



Precision-Therapy™



2mL to 10mL



Immediate bolus



Mechanical drive force



Flex-Therapy™



2mL to 10mL



Delayed or intermittent bolus,
constant infusion or variable rate



Electromechanical control



Flex-Therapy™ Mini



0.5mL to 2mL



Any bolus, constant
infusion or variable rate



Electromechanical control



Imperium™



0.5mL to 2mL



Constant basal insulin
with on-demand bolus



Electromechanical control



The First Ready-to-Inject, Fully Customizable Wearable Injectors



Unilife Wearable Injectors

3

Device-related steps to therapy

Supplied to user pre-filled and fully integrated with drug in ready-to-inject format



Competitor A

9

Device-related steps to therapy

Supplied to user in kit for assembly and loading of dose into device prior to use



Competitor B

9

Device-related steps to therapy

Supplied to user in kit for assembly and filling of device with syringe prior to use



Competitor information based on publicly available information as of August 2016

An Established Customer Base with Path to Commercial Sales



Slide reflects calendar years

Wearable-Focused. Disciplined Leadership. Positioned for Growth.



1.

Focus on industry-leading wearable injectors to leverage favorable market trends and address unmet needs for drug delivery

2.

Strong existing base of customers and programs with Amgen, Sanofi and AstraZeneca (MedImmune)

3.

Disciplined, experienced leadership focused on reducing cash burn and reliable program execution

4.

Partner with established, reliable industry leaders and material suppliers for production and supply continuity

5.

Build profitable organization on foundation of integrity, discipline, and innovative technology