UNILIFE CORP

FORM 8-K/A

(Amended Current report filing)

Filed 12/20/16 for the Period Ending 12/15/16

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/A

AMENDMENT NO. 1 TO CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): December 15, 2016

UNILIFE CORPORATION
(Exact name of Registrant as Specified in Charter)

Delaware	001-34540	27-1049354
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

250 Cross Farm Lane, York, Pennsylvania	17406
(Address of Principal Executive Offices)	(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))

Explanatory Note

On December 15, 2016, Unilife Corporation (the "Company") filed a Current Report on Form 8-K attaching remarks that were to be provided by the Company's Chief Executive Officer following the conclusion of the Company's annual stockholders meeting on the same day (the "Original Report"). This Current Report on Form 8-K/A amends the Original Report and is being filed solely to add forward looking statements disclosure to the Original Report which was inadvertently omitted from the Original Report. No other modifications have been made to the Original Report.

Item 7.01. Regulation FD Disclosure.

On December 15, 2016, following the conclusion of the annual stockholders meeting of Unilife Corporation, John Ryan will provide the remarks attached to this report as Exhibit 99.1 (the "Stockholder Presentation").

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.

Forward-Looking Statements

This report 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, those described in the "Risk Factors" set forth in our prospectus supplement, dated as of and filed with the SEC on February 22, 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 the Company's focus on wearable injector programs with key pharmaceutical customers may not be successful and/or result in the commercialization of the Company's products.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits .

Exhibit Number	Description
99.1	Unilife Corporation Stockholder 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: December 20, 2016

By: /s/ John Ryan
Name: John Ryan
Title: President and Chief Executive Officer

Exhibit 99.1

Unilife Annual Shareholder Meeting
John Ryan Remarks
December 15, 2016

Welcome everyone, thank you Mary Kate, and welcome Mike, Rose and Duane.

I have about five minutes of remarks, then would welcome questions and comments. The board and management will be here after the meeting and we encourage you to meet them after the meeting.

It has been a year of real transformation at Unilife, and on behalf of the management team we appreciate the confidence and support of you, our shareholders, and want to share with you our confidence in our future based on our foundation of industry-leading wearable injector technology and great customer relationships.

We provided a comprehensive update during our investor call on November 2 nd and I hope folks participated in the webcast on November 17 th for the presentation at the Jefferies Healthcare conference. I'm not going to cover in detail the items we focused on during those recent presentations today.

There are a few items that have been a particular area of focus for our shareholders that I will cover today: progress on our customer programs, our efforts to attract new customers and our employee engagement.

First, I am pleased to report that our base of existing customers in the wearable injector space continues to be very enthusiastic about our technology and on the development work of our teams, and we are pressing ahead on all cylinders to get these devices into the hands and onto the bodies of patients.

Our customers' teams and our teams are working together on our ongoing wearable injector programs, on items such as design verifications, clinical builds, and customer-specific customization of our wearable injectors. We have active programs for both our large volume (2 mL and up) and our small volume (less than 2 mL) wearable

injectors. We have already laid out our expected timeline for clinical supply and commercial supply of devices during our investor call, but I'll reiterate for the group that this coming year, in calendar 2017, we expect to commence supply of devices for clinical trials. Much of the work in our York facility is focused on the production of these clinical batches and the support of customer programs. In calendar 2018, we expect to begin commercial scale up and produce co mmercial equivalent devices for validation and customer pre-launch activities. 2019 is when we expect to begin commercial sales for anticipated patient use. Our engineering, production and quality teams are all working hard and focused on getting these d evices prepared for customer launches. I know that it is frustrating for investors not to have more precise specifics on individual customer programs, but it is very important that we honor our customers' confidentiality needs and for further news on the launch of customer therapies in our devices we will follow the lead of our customers. It is the right thing to do.

One items that just became public last month, on November 4 th , was the publication of a successful clinical study of our large volume delivery wearable injector. This study evaluated the efficacy of the device, and was a clinical trial with saline, thus testing the device itself. We were very pleased with the results, which showed the device to be effective, and this marked an important milestone for us as we work towards getting devices into patients' hands and on their bodies to deliver our customers' therapies.

Second, I'd like to spend a few minutes now on our work to attract new customers. We don't have any blockbuster announcements to make today, but I want to share with you that our team is hard at work to attract new customers. While we have existing contracts with three of the six largest biologics companies in terms of currently marketed, Phase 3 and Phase 2 pipelines, we are focusing on other large global biopharmas with multiple therapies that we think are excellent candidates for wearable injector delivery. We are in discussions with many of these companies. They have had understandable concerns about our ability to be reliable suppliers given some of the challenges we have faced over the past couple of years, but I'm pleased to report that

the disciplined and straightforward approach we are taking to our business coupled with our focus on wearable injector technology is a str ategy that is being received very favorably by prospective customers. You can be assured that we are hard at work to attract new customers and we are pleased to be doing so with what we are hearing time and time again is the best wearable injector technol ogy. We are going about it in a disciplined way and will make sure that any new contract is at attractive profit margins.

Finally, I'd like to talk about our employees – their commitment and engagement. We now have approximately 145 employees. One of the great successes we have had this past year is being able to reshape and refocus our company in a really significant way while continuing to have a team here at Unilife that is focused, engaged and productive. A year ago this time we had approximately 240 employees, and that was down from an all-time high of approximately 300 employees. Our team now consists of 140 employees, approximately 55 in King of Prussia where most of our product development engineers work, and approximately 85 in York, where our production associates work. One final thing before we turn to your questions. I want to share with our investors today that we have listed our York facility for sale as we move to a commercial manufacturing model with our wearable injector platform. We have always planned to use Contract Manufacturing Organizations for certain commercial scale manufacturing of our wearable injectors. Now that we are focusing just on our wearable injector platform, we have unused capacity in York. As we are working to sure up our balance sheet, we've listed the York facility for sale, and if we are able to sell the York facility at an attractive price point we think we will be best served by relocating our production facility to a smaller, less expensive facility that will allow us to still maintain the core production team that we now have for manufacture of clinical builds.

Thank you again for your attendance today, and we would be pleased to open up the meeting to your comments and remarks. We ask that you please step up, identify yourself by name so that everyone can hear your questions. Thank you.