

UNILIFE CORP

FORM 8-K (Current report filing)

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Sector	Healthcare
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**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 22, 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 1.01. Entry into a Material Definitive Agreement.

On February 22, 2016 (the “Closing Date”), Unilife Corporation (the “Company” or “we”) and Amgen Inc. (the “Counterparty”) announced the formation of a strategic collaboration for the Counterparty’s use of the Company’s injectable drug delivery systems with the Counterparty’s product portfolio. In connection with the strategic collaboration, the Company and certain of its subsidiaries entered into a Securities Purchase Agreement (the “SPA”) with the Counterparty and certain related documents (collectively, the “Transaction Documents”), as more fully described below. The formation of the strategic collaboration with the Counterparty marks the completion of the Company’s previously announced review of strategic alternatives.

Securities Purchase Agreement

Pursuant to the SPA, the Counterparty agreed to purchase from the Company a new series of 6% Senior Secured Convertible Notes Due 2023 in the aggregate original principal amount of up to \$55,000,000 (each, a “Note” and, collectively, the “Notes”). The Notes are convertible into the Company’s common stock, \$0.01 par value per share (the “Common Stock”), and mature on February 22, 2023 (the “Maturity Date”) in accordance with the terms and conditions of the Notes, as more fully described below.

The Notes may be issued in up to three separate closings. The Company issued to the Counterparty the first Note in the aggregate original principal amount of \$30,000,000 on the Closing Date (the “2016 Convertible Note”) and the Counterparty paid to the Company \$30,000,000 in exchange therefor. The Counterparty may purchase up to an additional \$25,000,000 in Notes over the next two years, \$15,000,000 of which may be purchased in January 2017 (the “2017 Convertible Note”), and \$10,000,000 of which may be purchased in January 2018 (the “2018 Convertible Note”).

The SPA contains customary representations and warranties. The SPA also contains certain covenants including, among others, covenants related to the Company’s use of the proceeds from the sale of the Notes to the Counterparty solely for operational purposes and not for the repayment of any outstanding indebtedness of the Company owed to the Lender (as defined below).

The SPA provides the Counterparty with certain registration rights, including the right to demand the registration of its securities and to join or “piggyback” on other registrations pursued by the Company. The Company agreed to pay all costs and expenses incurred in connection with such registrations.

In connection with the transactions contemplated by the SPA, the Company granted the Counterparty exclusive rights to the Company’s wearable injectors within select drug classes for use with certain Counterparty assets, while preserving rights the Company previously granted to other customers. The Company has also granted the Counterparty non-exclusive rights to all of the Company’s proprietary delivery systems within the therapeutic areas of oncology, inflammation, bone health, nephrology, cardiovascular and neuroscience. On the Closing Date, the Counterparty paid to the Company a non-refundable \$20,000,000 fee (the “License Fee”) in consideration for such licenses.

The Counterparty may not develop, manufacture or have manufactured (except by the Company) more than 20% of the Counterparty's annual volume needs for the Company's wearable injectors so long as the Company satisfies certain conditions.

The transactions contemplated by the SPA provide for the development, production and supply of certain Company delivery systems. Development programs for the Company's wearable injectors will commence in 2016.

The 2016 Convertible Note

As set forth above, on the Closing Date, the Company issued to the Counterparty the 2016 Convertible Note.

Interest under the 2016 Convertible Note accrues at a rate of 6% per year and will be paid quarterly in arrears through the addition of the amount of such interest to the then outstanding principal amount. All or part of the principal and accrued interest will be repaid through (i) discounted pricing on purchases by the Counterparty of the Company's products, (ii) credits taken by the Counterparty against development and customization fees for devices, and (iii) credits against per-unit royalties otherwise payable to the Company for the manufacture and sale of the Company's products. In addition, the Company has the right to prepay in cash all or part of the principal and accrued interest at any time upon 15 business days' prior notice, subject to the Counterparty's conversion right with respect to the contemplated prepayment amount. The Company is required to pay in cash any amounts of principal and accrued interest outstanding at the Maturity Date.

The 2016 Convertible Note is convertible at the Counterparty's election into shares of the Company's Common Stock at any time after the Closing Date and prior to the Maturity Date, at a price per share that is 90% of the volume weighted average price of such shares during the twenty (20) trading days preceding the applicable conversion date (the "Discounted Sale Price"), subject to a floor price of \$1.25 per share (the "Conversion Rate Floor Price"). The Conversion Rate Floor Price is subject to customary adjustments for certain capital events.

The Counterparty may cause the redemption of the 2016 Convertible Note upon any event of default by the Company. Events of default under the 2016 Convertible Note include, among others, a failure by the Company to convert the 2016 Convertible Note upon proper notice by the Counterparty or pay principal and interest on the 2016 Convertible Note when due; an acceleration of any other indebtedness under the Amended Credit Agreement (as defined below) or other indebtedness of the Company in excess of \$1 million; a bankruptcy of the Company; a judgment against the Company in excess of \$1 million; a representation or warranty made in the Transaction Documents is materially false or misleading when made; a material breach by the Company of a covenant or other term or condition in the Transaction Documents; the Transaction Documents cease to be effective; the termination or amendment of the Eighth Amendment to the Credit Agreement or the Sixth Amendment to the Royalty Agreement (each as defined below); and the incurrence of a lien on collateral that is not a permitted lien. The Company is required to redeem for cash the 2016 Convertible Note upon a change of control of the Company in an amount equal to 101% of the aggregate principal and accrued interest outstanding as of the change of control.

The 2016 Convertible Note also provides the Counterparty with certain rights to acquire additional shares of Common Stock or other securities or assets of the Company, as applicable, in the event: (i) the Company grants, issues or sells any options, convertible securities or rights to purchase stock, warrants, securities or other property pro rata to the holders of Common Stock; or (ii) the Company makes certain other distributions to Company stockholders such that, in the case of (i) or (ii), the Counterparty receives, in addition to the shares of Common Stock otherwise issuable upon conversion of the 2016 Convertible Note, the shares of Common Stock or other securities or assets, as applicable, that the Counterparty would have been entitled to receive if the Counterparty had converted the 2016 Convertible Note into Common Stock immediately prior to such event.

The 2016 Convertible Note is secured by certain inventory and intellectual property assets related to a specific device being licensed to the Counterparty (the "Collateral"). The Counterparty has agreed to preserve license rights granted to other customers for any license rights granted prior to a foreclosure. The terms and conditions of the 2017 Convertible Note and the 2018 Convertible Note, if purchased by the Counterparty, are substantially the same as the terms and conditions of the 2016 Convertible Note, except that the "Conversion Rate Floor Price" will be the greater of (x) \$1.25, (y) the closing sale price of the Common Stock on the trading day preceding the issuance date, and (z) the book value per share of Common Stock on the trading day immediately preceding the issuance date.

Stockholder approval is not required for the issue of the 2016 Convertible Note to the Counterparty or for the issue of shares of Common Stock on conversion of the 2016 Convertible Note. The issue of the 2016 Convertible Note is not being made to a class of stockholders.

Amendment to OrbiMed Credit Agreement and Royalty Agreement and Grant of Warrant

In connection with the offering of the Notes and certain requirements in the SPA, on the Closing Date, the Company, Unilife Medical Solutions, Inc. (the "Borrower"), a subsidiary of the Company, and certain of the Company's other subsidiaries entered into the eighth amendment (the "Eighth Amendment to the Credit Agreement") to that certain Credit Agreement, dated March 12, 2014, as amended (the "Amended Credit Agreement"), with ROS Acquisition Offshore LP (together with its affiliates, successors, transferees and assignees, the "Lender"), an affiliate of OrbiMed Advisors LLC. Pursuant to and subject to the terms of the Eighth Amendment to the Credit Agreement, the Lender agreed to, among others, (i) defer all obligations of the Borrower to pay interest to the Lender for the period from January 1, 2016 through the two year anniversary of the Closing Date at the rate specified in the Amended Credit Agreement, which interest will be added to the outstanding principal amount of the loan on the last day of each interest period; (ii) enable the Counterparty to take a security interest in the Collateral; and (iii) remove the minimum cash receipts covenant for all future periods. In addition, under the terms of the Eighth Amendment to the Credit Agreement, the Company will make, prior to March 30, 2016, such management changes as are requested by the Lender.

In addition, on the Closing Date, the Company, the Borrower and certain of the Company's other subsidiaries entered into the sixth amendment (the "Sixth Amendment to the Royalty Agreement") to that certain royalty agreement, dated March 12, 2014, as amended, with Royalty Opportunities S.à r.l. ("ROS"). Pursuant to and subject to the terms of the Sixth Amendment to the Royalty Agreement, ROS agreed to waive any rights to royalty payments otherwise payable as a result of the License Fee and the proceeds of the Notes, and to defer royalty payments payable on revenues received by the Company from the Counterparty until after the end of the first fiscal quarter in which the Company sells a commercial quantity of devices developed for Counterparty.

In connection with entering into the Eighth Amendment to the Credit Agreement and the Sixth Amendment to the Royalty Agreement, the Company issued to ROS warrants to purchase 16,739,805 shares of Common Stock, with an exercise price of \$1.25 per share, subject to adjustment for certain events, which may be exercised at any time and from time to time until February 22, 2026 (the “Warrants”).

In lieu of the paying the exercise price in cash, the holder of the Warrants may elect to “net exercise” the Warrants in accordance with its terms. The holder of the Warrants is entitled to certain demand and “piggyback” registration rights.

A prospectus supplement relating to the offering of the Warrants and the shares of Common Stock issuable under the Warrants has been filed with the Securities and Exchange Commission.

Stockholder approval is not required for the issue of the Warrants or for the issue of shares of Common Stock on exercise of the Warrants. The issue of the Warrants is not being made to a class of stockholders.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

Reference is made to the disclosure set forth under Item 1.01 of this Current Report on Form 8-K, which disclosure is incorporated herein by reference.

Item 3.02. Unregistered Sales of Equity Securities.

Reference is made to the disclosure set forth under Item 1.01 of this Current Report on Form 8-K, which disclosure is incorporated herein by reference.

The Notes were offered and sold in reliance upon exemptions from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), and Rule 506 of Regulation D promulgated under the Securities Act (“Regulation D”). The Lender has represented that it is an accredited investor, as that term is defined in Regulation D, and has acquired the securities for investment purposes only and not with a view to or for sale in connection with any distribution thereof, and were not issued through any general solicitation or advertisement.

Item 8.01. Other Events.

In addition, on the Closing Date, the Company issued a press release announcing the Company’s entering into the transactions described in this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.1.

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 the “Risk Factors” set forth in the prospectus supplement, dated February 22, 2016, relating to the offering of the Warrants and the shares of Common Stock issuable under the Warrants, 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 the Counterparty may not purchase the 2017 Convertible Note and/or the 2018 Convertible Note.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
5.1	Opinion of Duane Morris LLP.
23.1	Consent of Duane Morris LLP (included as part of Exhibit 5.1).
99.1	Press Release, dated February 22, 2016.

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: February 22, 2016

By: /s/ Alan Shortall

Name: Alan Shortall

Title: Chairman and Chief Executive Officer

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February 22, 2016

Unilife Corporation
250 Cross Farm Lane
York, PA 17406

Re: Unilife Corporation (the “Corporation”) – Form S-3 (Registration File No. 333-197122) (the “Registration Statement”)

Ladies and Gentlemen:

We have acted as special counsel to the Corporation in connection with the offering directly to Royalty Opportunities S.à r.l. (the “Purchaser”) by the Corporation of a warrant (the “Warrant”) to purchase from the Corporation 16,739,805 shares (the “Shares”) of the Corporation’s common stock, par value \$0.01 per share. The Warrant is being offered and sold pursuant to an Eighth Amendment to the Credit Agreement, dated February 22, 2016, by and between the Corporation and the Purchaser (the “Amendment”).

As special counsel to the Corporation, we have supervised all corporate proceedings in connection with the preparation and filing of the prospectus supplement, dated as of the date hereof (the “Prospectus Supplement”) and the Amendment. We bring to your attention that we did not supervise or prepare the prospectus dated October 3, 2014 included in the Registration Statement.

For purposes of rendering this opinion, we have examined originals or copies (certified or otherwise identified to our satisfaction) of:

a. The Amendment;

D UANE M ORRIS LLP

30 SOUTH 17TH STREET PHILADELPHIA, PA 19103-4196

PHONE: +1 215 979 1000 FAX: +1 215 979 1020

- b. The Certificate of Incorporation of the Corporation, as amended, certified by the Secretary of State of the State of Delaware;
- c. The Amended and Restated Bylaws of the Corporation; and
- d. Resolutions of the Board of Directors of the Corporation, as attested by the Secretary of the Corporation.

We have also examined such other certificates of public officials, such certificates of executive officers of the Corporation and such other records, agreements, documents and instruments as we have deemed relevant and necessary as a basis for the opinions hereinafter set forth.

In such examination, we have assumed: (i) the genuineness of all signatures (whether or not such signatures have been affixed electronically) and that all signatures have not been revoked by the signatory thereof as of the time of the delivery of this opinion, (ii) the legal capacity of all natural persons, (iii) the authenticity of all documents submitted to us as originals, (iv) the conformity to original documents of all documents submitted to us as certified, conformed or other copies and the authenticity of the originals of such documents and (v) that all records and other information made available to us by the Corporation on which we have relied are complete in all material respects. As to all questions of fact material to these opinions, we have relied solely upon the above-referenced certificates or comparable documents and upon the representations and warranties contained in the Amendment and other documents delivered pursuant thereto, have not performed or had performed any independent research of public records and have assumed that certificates of or other comparable documents from public officials dated prior to the date hereof remain accurate as of the date hereof.

Based upon the foregoing, we are of the opinion that:

- 1. The Warrant, when issued in accordance with the Amendment, constitutes a valid and binding agreement of the Corporation enforceable against the Corporation in accordance with its terms.
- 2. The Shares, upon issuance and delivery upon exercise of the Warrant in accordance with its terms, will be validly issued, fully paid and nonassessable.

The foregoing opinion is limited to the laws of the States of Delaware and New York, and we do not express any opinion herein concerning any other law.

The opinion expressed herein is rendered as of the date hereof and is based on existing law, which is subject to change. Where our opinion expressed herein refers to events to occur at a future date, we have assumed that there will have been no changes in the relevant law or facts between the date hereof and such future date. We do not undertake to advise you of any changes in the opinion expressed herein from matters that may hereafter arise or be brought to our attention or to revise or supplement such opinions should the present laws of any jurisdiction be changed by legislative action, judicial decision or otherwise.

Our opinion expressed herein is limited to the matters expressly stated herein, and no opinion is implied or may be inferred beyond the matters expressly stated.

We hereby consent to the use of this letter as an exhibit to the Registration Statement and to any and all references to our firm in the prospectus supplement that is a part of the Registration Statement. In giving this consent, we do not admit that we are “experts” within the meaning of Section 11 of the Securities Act or within the category of persons whose consent is required under Section 7 of the Securities Act.

Very truly yours,

/s/ Duane Morris LLP



Unilife and Amgen Enter Strategic Collaboration for Injectable Drug Delivery Systems

Amgen to invest up to \$75 million in leading technology platform

Collaboration includes license agreement and master development and supply agreement

York, PA. – February 22, 2016: Unilife Corporation (NASDAQ:UNIS, ASX:UNIS) today announced a strategic collaboration with Amgen (NASDAQ:AMGN), a leading biotechnology company, for injectable drug delivery systems. The collaboration, which includes licensing, investment, development and supply agreement components, is centered upon the use of Unilife’s portfolio of prefilled, customizable wearable injectors for medicines to enhance the patient experience.

Under the terms of the collaboration, Unilife has granted Amgen exclusive rights to Unilife’s wearable injectors within select drug classes for use with certain Amgen assets, while preserving rights previously granted to other Unilife customers. Unilife has also granted Amgen non-exclusive rights to all proprietary Unilife delivery systems within the therapeutic areas of oncology, inflammation, bone health, nephrology, cardiovascular and neuroscience.

“Unilife looks forward to a long-term strategic collaboration with Amgen to drive value for patients, prescribers and payers,” said Ian Hanson, senior vice president and general manager of Unilife’s Wearable Injector business unit. “Unilife is pleased to advance its leadership position in the wearable injectors market to meet growing demand for biologics and other medicines. Our prefilled, pre-assembled and ready-to-inject delivery systems are easy-to-use and enhance patient experience.”

“We are pleased to enter this collaboration with Unilife,” said Alison Moore, senior vice president of Process Development at Amgen. “One important pillar of Amgen’s strategy is to invest in leading drug delivery technologies to more effectively meet the needs of patients suffering from serious illnesses. Unilife continues to develop technology that could provide patients with innovative and meaningful enhancements to drug administration.”

Under the strategic collaboration, Unilife can receive up to \$75 million. At closing, Amgen paid a nonrefundable \$20 million license fee and purchased a \$30 million senior secured convertible note from Unilife. Amgen may purchase up to an additional \$25 million in senior secured convertible notes over the next two years (\$15 million in January 2017 and \$10 million in January 2018). These payments are in addition to Amgen’s \$15 million payment to Unilife in connection with the exclusivity letter entered into on December 31, 2015.

In addition to these payments, Unilife expects to generate future revenue from the strategic collaboration with Amgen. The collaboration includes a master development and supply agreement that captures key terms for the development, production and supply of Unilife delivery systems. Development programs will commence in 2016.

About Unilife

Unilife Corporation (NASDAQ:UNIS / ASX: UNIS) is a U.S.-based developer and commercial supplier of injectable drug delivery systems. Unilife’s portfolio of innovative, differentiated products includes prefilled syringes with automatic needle retraction, drug reconstitution delivery systems, auto-injectors, wearable injectors, insulin delivery systems, ocular delivery systems and novel systems. Products within each platform are customizable to address specific customer, drug and patient requirements. Unilife’s global headquarters and manufacturing facilities are located in York, Penn. For more information, visit www.unilife.com

General: UNIS-G

Investor Contacts (U.S.):

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Unilife Corporation
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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, those described in the "Risk Factors" set forth in Unilife's prospectus supplement, dated as of and filed with the U.S. Securities and Exchange Commission on February 22, 2016, and those described from time to time in other reports which we file with the U.S. Securities and Exchange Commission.