
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 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): **December 18, 2018**

STRONGBRIDGE BIOPHARMA plc

(Exact Name of Registrant as Specified in Its Charter)

Ireland

(State or Other Jurisdiction of Incorporation)

001-37569

(Commission File Number)

98-1275166

(IRS Employer Identification No.)

900 Northbrook Drive

Suite 200

Trevose, PA

(Address of Principal Executive Offices)

19053

(Zip Code)

(610) 254-9200

(Registrant's Telephone Number, including Area Code)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.02. Termination of a Material Definitive Agreement

On December 18, 2018, Strongbridge Biopharma plc (the “Company”) along with Strongbridge U.S. Inc. (“SBUS”), Cortendo Cayman Ltd., Strongbridge Ireland Limited (“Strongbridge Ireland”) and Cortendo AB (publ), each a subsidiary of the Company (collectively, the “Subsidiaries”), entered into a payoff letter (the “Payoff Letter”) with CRG Servicing LLC (“CRG”), as administrative agent, pursuant to which the Company and the Subsidiaries agreed to pay off and thereby terminate the Term Loan Agreement, dated as of July 14, 2017 (as modified by the Consent to Term Loan Agreement, dated as of January 3, 2018, and as amended by Amendment No. 1 to Term Loan Agreement, dated as of January 16, 2018 and Amendment No. 2 to Term Loan Agreement, dated as of June 6, 2018), by and among the Company, the Subsidiaries, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto (the “Lenders”) and CRG, as administrative agent and collateral agent for the Lenders (the “CRG Loan Agreement”).

Pursuant to the terms of the Payoff Letter, SBUS will pay, on or about December 18, 2018, a total of \$100,269,107.83 (the “Payoff Amount”) to the Lenders, representing the principal balance, accrued and unpaid interest, costs and expenses and a portion of the fees outstanding under the CRG Loan Agreement. In addition, the Company will issue an aggregate of 656,929 ordinary shares of the Company (the “Payoff Shares”) with an approximate aggregate value of \$3,000,000 to certain designees of CRG (the “CRG Designees”) in satisfaction of certain prepayment and back-end fees payable to the Lenders under the CRG Loan Agreement, pursuant to the terms of a securities purchase agreement, by and among the Company and the CRG Designees.

Upon payment of the Payoff Amount to the Lenders and the issuance of the Payoff Shares to the CRG Designees, the CRG Loan Agreement and the Loan Documents (as such term is defined in the CRG Loan Agreement), other than the warrants previously issued to the CRG Designees and currently outstanding, will be terminated, all outstanding indebtedness and obligations of the Company and the Subsidiaries (the “Loan Obligations”) owing to the Lenders and CRG under the CRG Loan Agreement and the other Loan Documents will be satisfied and paid in full, all liens and security interests securing the Loan Obligations will be fully released, and all of CRG’s and each Lender’s commitments to extend further credit to the Company and the Subsidiaries under the CRG Loan Agreement and the Loan Documents will be terminated.

Item 2.01. Completion of Acquisition or Disposition of Assets

The Macrilen Acquisition Agreement

On December 18, 2018, the Company exercised its put option in accordance with the previously disclosed Macrilen Acquisition Agreement, dated as of October 31, 2018, with Novo Nordisk Healthcare AG, a Swiss corporation (“Buyer”), (the “Macrilen Acquisition Agreement”) and completed the previously announced sale of the entire issued share capital of Strongbridge Ireland, which holds the pharmaceutical product for assessing growth hormone deficiency in adults and children known as Macrilen. Capitalized terms used herein and not otherwise defined have the meaning given to them in the Macrilen Acquisition Agreement.

Pursuant to the terms of the Macrilen Acquisition Agreement, Buyer paid the Company \$145,000,000, the exercise price of the put option, and the Company is also entitled to receive royalty payments from the sale of Macrilen. Between January 1, 2019 and December 31, 2021, Buyer will pay to the Company 12% of Annual Net Sales of Macrilen in the United States. Between January 1, 2022 and December 31, 2027, Buyer will pay to the Company (i) 4% of any portion of Annual Net Sales in the United States up to \$100,000,000 and (ii) 8% of any portion of Annual Net Sales in the United States greater than \$100,000,000. The royalty payments are subject to certain conditions and reductions, including if Macrilen is no longer covered by a Valid Claim of a Patent in the United States or Buyer or its Affiliates no longer hold exclusive marketing rights granted by the United States Food and Drug Administration (“FDA”).

In connection with the closing of the transaction contemplated by the Macrilen Acquisition Agreement, on December 18, 2018, SBUS entered into a Services Agreement (the “Services Agreement”) with Novo Nordisk Inc., a subsidiary of Buyer (“NNI”), pursuant to which 23 field-based employees of SBUS will provide services to NNI, including to promote Macrilen in the United States and Canada for a period of three years.

In connection with the closing of the transaction contemplated by the Macrilen Acquisition Agreement, on December 18, 2018, SBUS entered into a Medical Team Services Agreement (the “Medical Team Services Agreement”) with NNI, pursuant to which three field-based medical liaison employees of SBUS will provide certain medical liaison services to NNI on a part-time basis, including the handling of medical information requests and providing training support, for a period of three months.

In connection with the closing of the transaction contemplated by the Macrilen Acquisition Agreement, on December 18, 2018, SBUS entered into a Transitional Services Agreement (the “Transitional Services Agreement”) with Buyer, pursuant to which SBUS will provide certain of the activities required to be undertaken by the Product NDA holder (on behalf of Buyer, in Buyer’s capacity as the Product NDA holder), including product supply, adverse experience reporting, quarterly and annual reports to the FDA, handling and tracking of complaints, sample tracking, and communication and providing information to and with health care professionals, customers and the FDA. SBUS will provide such services for the time periods agreed to in the Transitional Services Agreement.

In connection with the closing of the transaction contemplated by the Macrilen Acquisition Agreement, on December 18, 2018, SBUS entered into an Inventory Purchase and Sale Agreement with Strongbridge Ireland, pursuant to which all inventory associated with Macrilen was purchased by Strongbridge Ireland.

The foregoing description of the Macrilen Acquisition Agreement is not complete and is subject to and qualified in its entirety by reference to the full text of the Macrilen Acquisition Agreement filed as Exhibit 2.1 to the Company’s Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission (the “SEC”) on October 31, 2018, and incorporated herein by reference.

Investor Agreement

On December 18, 2018, the Company sold 5,242,000 ordinary shares of the Company to Novo Nordisk A/S, a company organized and existing under the law of Denmark (“Novo Nordisk”), at a purchase price of \$7.00 per share and an aggregate purchase price of \$36,694,000, in accordance with the previously disclosed Share Purchase Agreement, dated as of October 31, 2018, entered into by the Company and Novo Nordisk (the “Investor Agreement”). The shares were sold in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended, pursuant to Section 4(a)(2).

In connection with the closing of the transaction contemplated by the Investor Agreement, on December 18, 2018, the Company entered into a Registration Rights Agreement with Novo Nordisk (the "Registration Rights Agreement"), pursuant to which (i) Novo Nordisk agreed, subject to certain exceptions, not to transfer the ordinary shares purchased from the Company for a period of 180 days following the closing of the transactions contemplated by the Investor Agreement, and (ii) the Company provided Novo Nordisk with certain demand and piggyback registration rights.

The Company used a portion of the net proceeds from the transactions contemplated by the Macrilen Acquisition Agreement and the Investor Agreement to pay off the CRG Loan Agreement, as described further in Item 1.02 of this Current Report on Form 8-K.

The foregoing description of the Investor Agreement, including the form of Registration Rights Agreement, which is an exhibit to the Investor Agreement, is not complete and is subject to and qualified in its entirety by reference to the full text of the Investor Agreement, including the form of Registration Rights Agreement, filed as Exhibit 2.2 to the Company's Current Report on Form 8-K filed with the SEC on October 31, 2018, and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

- 2.1* Macrilen Acquisition Agreement, dated as of October 31, 2018, between Strongbridge Biopharma plc and Novo Nordisk Healthcare AG (incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed on October 31, 2018).
- 2.2* Share Purchase Agreement, dated as of October 31, 2018 between Strongbridge Biopharma plc and Novo Nordisk A/S (incorporated by reference to Exhibit 2.2 of the Company's Current Report on Form 8-K filed on October 31, 2018).

* Certain schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedules so furnished.

COMPANY CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Current Report on Form 8-K contains forward-looking statements. All statements, other than statements of historical or current facts, are forward-looking statements. In many cases, you can identify forward-looking statements by terminology such as “will” or the negative of that term or other words of similar import, although some forward-looking statements are expressed differently. These statements reflect the current views of the Company concerning future events and are based on a number of assumptions that could ultimately prove inaccurate. Forward-looking statements are subject to risks and uncertainties. If one or more of these risks or uncertainties materialize, or if management’s underlying assumptions prove to be incorrect, actual results may differ materially from those contemplated by a forward-looking statement. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, without limitation: the amount of royalty payments the Company receives under the Macrilen Acquisition Agreement; significant transaction costs; unknown liabilities; other business effects, including the effects of industry, market, economic, political or regulatory conditions; and other risks and uncertainties discussed in the Company’s filings with the SEC, including in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and subsequent quarterly reports on Form 10-Q, which are available online at www.sec.gov, www.strongbridgebio.com or by request from the Company. In addition, in light of these risks and uncertainties, the matters referred to in the Company’s forward-looking statements may not occur. The Company undertakes no obligation to publicly update or revise any forward-looking statement as a result of new information, future events or otherwise, except as may be required by law.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
2.1*	<u>Macrilen Acquisition Agreement, dated as of October 31, 2018, between Strongbridge Biopharma plc and Novo Nordisk Healthcare AG (incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed on October 31, 2018).</u>
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SIGNATURE

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.

Dated: December 19, 2018

STRONGBRIDGE BIOPHARMA PLC

By: /s/ A. Brian Davis

Name: A. Brian Davis

Title: Chief Financial Officer