

Seres Therapeutics, Inc.
Form 8-K
January 11, 2016

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): January 9, 2016

SERES THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-37465
(Commission
File Number)
215 First Street

27-432690
(I.R.S. Employer
Identification No.)

Edgar Filing: Seres Therapeutics, Inc. - Form 8-K

Cambridge, MA 02142

(Address of principal executive offices) (Zip Code)

(617) 945-9626

(Registrant's telephone number, include area code)

N/A

(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))

Item 1.01 Entry into a Material Definitive Agreement.

On January 9, 2016 (the Effective Date), Seres Therapeutics, Inc. (the Company) entered into a Collaboration and License Agreement (the License Agreement) with Nestec Ltd. (Nestlé), an affiliate of Nestlé Health Science, and, solely for the purpose of the integration clause of the License Agreement, Nestlé Health Science SA. Pursuant to the License Agreement, the Company granted to Nestlé, under certain of the Company's patent rights and know how: (i) an exclusive, royalty-bearing license to develop and commercialize certain products based on the Company's microbiome technology that are developed for the treatment of *Clostridium difficile* infection (CDI), including the Company's products SER-109 and SER-262; the treatment of inflammatory bowel disease, including ulcerative colitis and Crohn's disease (IBD), including the Company's products SER-287 and SER-301; or solely if the Parties mutually agree, other indications, in countries outside of the United States and Canada (the Licensed Territory); (ii) an exclusive, royalty-bearing license to develop and commercialize SER-109, SER-262, SER-287 and SER-301 and, if the parties mutually agree, other specific products added under the License Agreement (collectively, the Collaboration Products), for any indications in the Licensed Territory; and (iii) a non-exclusive license to export, develop and make Collaboration Products in the licensed fields worldwide solely for commercialization in the licensed fields and in the Licensed Territory.

The License Agreement sets forth the parties' respective obligations for development, commercialization, regulatory and manufacturing and supply activities for the Collaboration Products with respect to the licensed fields and the Licensed Territory. Pursuant to the License Agreement, the parties' development activities will be governed by global and regional development plans, including the conduct of additional clinical studies. The Company agreed to manufacture and supply Collaboration Products to support development and commercialization of Collaboration Products in the licensed fields and in the Licensed Territory. The Company agreed to use diligent efforts to develop Collaboration Products under a global development plan and to obtain approval for such Collaboration Products in the European Union. In exchange for the grant of such licenses under the License Agreement, Nestlé agreed to pay the Company an upfront cash payment of \$120 million. Nestlé also agreed to pay the Company development, approval and commercial milestones totaling up to \$660 million. The Company expects to receive a total of \$30 million in milestone payments in 2016 associated with the planned initiation of a Phase 1b study for SER-262 in CDI and the anticipated initiation of the Phase 3 trial for SER-109 in CDI. Nestlé is also obligated to pay sales-based milestones that may total in the aggregate up to \$1.125 billion. Nestlé agreed to pay to the Company tiered royalties, at percentages ranging from the high single digits to high teens, of net sales of Collaboration Products in the Licensed Territory.

For development of Collaboration Products for IBD under a global development plan, the Company is obligated to pay the costs of clinical trials of such products up to and including Phase 2 clinical trials, and 67% of the costs for Phase 3 and other clinical trials of such products, with Nestlé bearing the remaining 33% of such costs. For other clinical development of Collaboration Products for IBD, the Company will pay the costs of such activities to support approval in the United States and Canada, and Nestlé bears the costs of such activities to support approval of Collaboration Products in the Licensed Territory.

With respect to development of Collaboration Products for CDI under a global development plan, the Company agreed to pay all costs of an ongoing Phase 2 clinical trial for SER-109 and of Phase 3 clinical trials for SER-109. The Company agreed to bear all costs of conducting any Phase 1 or Phase 2 clinical trials under a global development plan for Collaboration Products other than SER-109 for CDI. The Company agreed to pay 67% and Nestlé agreed to pay 33% of other costs of Phase 3 clinical trials conducted for Collaboration Products other than SER-109 for CDI under a global development plan. For other clinical development of Collaboration Products for CDI, the Company agreed to pay costs of such development activities to support approval in the United States and Canada, and Nestlé agreed to bear the cost of such activities to support approval of Collaboration Products in the Licensed Territory.

The License Agreement continues in effect until terminated by either party on the following bases: (i) Nestlé may terminate the License Agreement in the event of serious safety issues related to any of the Collaboration Products;

(ii) the Company may terminate the License Agreement if Nestlé challenges the validity or enforceability of any of the Company's licensed patents; and (iii) either party may terminate the License Agreement in the event of the other party's uncured material breach or insolvency. Upon termination of the License Agreement, all licenses granted to Nestlé by the Company will terminate, and all rights in and to the Collaboration Products in the Licensed Territory will revert to the Company. If the Company commits a material breach of the License Agreement, Nestlé may elect not to terminate the License Agreement but instead apply specified adjustments to its payment obligations and other terms and conditions of the License Agreement.

The License Agreement contains customary representations and warranties by the parties, intellectual property protection provisions, certain indemnification rights in favor of each party and customary confidentiality provisions and limitations of liability.

Forward-Looking Statements

This Current Report on Form 8-K (the **Current Report**) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the amount and timing of potential milestone payments.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding, which may not be available; our limited operating history; the unpredictable nature of our early stage development efforts for marketable drugs; the unproven approach to therapeutic intervention of our microbiome therapeutics; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; potential delays in enrollment of patients which could affect the receipt of necessary regulatory approvals; potential delays in regulatory approval, which would impact the ability to commercialize our product candidates and affect our ability to generate revenue; any fast track or Breakthrough Therapy designation may not lead to faster development, regulatory approval or marketing approval; our possible inability to receive orphan drug designation should we choose to seek it; our reliance on third parties to conduct our clinical trials and the potential for those third parties to not perform satisfactorily; our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts; our lack of experience in manufacturing our product candidates; the potential failure of our product candidates to be accepted on the market by the medical community; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; failure to compete successfully against other drug companies; potential competition from biosimilars; failure to obtain marketing approval internationally; post-marketing restrictions or withdrawal from the market; anti-kickback, fraud, abuse, and other healthcare laws and regulations exposing us to potential criminal sanctions; recently enacted or future legislation; compliance with environmental, health, and safety laws and regulations; protection of our proprietary technology; protection of the confidentiality of our trade secrets; changes in United States patent law; potential lawsuits for infringement of third-party intellectual property; our patents being found invalid or unenforceable; compliance with patent regulations; claims challenging the inventorship or ownership of our patents and other intellectual property; claims asserting that we or our employees misappropriated a third-party's intellectual property or otherwise claiming ownership of what we regard as our intellectual property; adequate protection of our trademarks; ability to attract and retain key executives; managing our growth could result in difficulties; risks associated with international operations; potential system failures; the price of our common stock may fluctuate substantially; our executive officers, directors, and principal stockholders have the ability to control all matters submitted to the stockholders; a significant portion of our total outstanding shares are eligible to be sold into the market in the near future; unfavorable or lacking analyst research or reports; and we may be subject to securities class action litigation. These and other important factors discussed under the caption **Risk Factors** in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on November 12, 2015 and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Current Report.

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.

SERES THERAPEUTICS, INC.

Date: January 11, 2016

By: /s/ Eric D. Shaff

Name: Eric D. Shaff

Title: Executive Vice President and Chief Financial Officer