
**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): February 25, 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)

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

215 First Street
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))
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Item 2.02. Results of Operations and Financial Condition.

On February 25, 2016, Seres Therapeutics, Inc. (the "Company") announced its financial results for the year and quarter ended December 31, 2015. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on February 25, 2016

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: February 25, 2016

By: /s/ Eric D. Shaff

Name: Eric D. Shaff

Title: Chief Financial Officer and Executive Vice President

EXHIBIT INDEX

**Exhibit
No.**

Description

99.1 Press Release issued on February 25, 2016



Seres Therapeutics Reports Fourth Quarter and Full Year 2015 Financial Results and Provides Business Update

Company highlights progress in commercial preparedness, pipeline expansion

Strong financial position; existing cash expected to support operations well into 2018

CAMBRIDGE, Mass.—(BUSINESS WIRE)—Feb. 25, 2016— Seres Therapeutics Inc. (NASDAQ: MCRB), a leading microbiome therapeutics platform company, today reported financial results and provided a business update for the fourth quarter and full year ended December 31, 2015.

The company highlighted the progress it made in advancing its commercial strategy and expanding its pipeline into new indications.

“The fourth quarter 2015 and early 2016 has been a period of unprecedented growth for Seres in which we made tremendous progress in preparing for the expected commercialization of our therapies for *Clostridium difficile* (CDI) infection, while also expanding into new therapeutic areas with our Ecobiotic® microbiome therapeutics platform,” said Roger Pomerantz, M.D., President, CEO and Chairman of Seres. “Our strategic agreement with Nestlé Health Science for our CDI and Inflammatory Bowel Disease (IBD) product candidates provides global reach outside of the US and Canada and further strengthens our financial position. In parallel, the initiation of our Phase 1b SER-287 study in ulcerative colitis (UC) marks the first time a microbiome therapeutic candidate has been tested in a chronic disease. In 2016 we anticipate several important milestones, including SER-109 Phase 2 results in recurrent CDI infection in mid-2016, the initiation of a Ph1b study for SER-262, a fermented synthetically derived therapeutic candidate, in primary recurrent CDI in mid-2016, and the initiation of a Phase 3 study for SER-109 in recurrent CDI infection in the second half of 2016.”

Fourth Quarter and Recent Business Highlights:

- **Initiation of SER-287 Phase 1b study in ulcerative colitis (December 2015):** SER-287 is an oral capsule developed using Seres’ proprietary microbiome therapeutics

platform. The randomized, placebo-controlled multiple dose study will be conducted in 20 centers around the U.S. and is expected to enroll up to 55 subjects with active mild-to-moderate UC. The Phase 1b study will evaluate the change in the microbiome resulting from SER-287 treatment as well as clinical response, mucosal healing, and metabolomic, immunological and safety findings. UC is a prevalent and serious chronic condition affecting approximately 700,000 people in the United States alone. Growing evidence indicates that UC is marked by an imbalance of bacteria, or dysbiosis, in the gut. Published clinical reports suggest that modulation of the microbiome through repetitive fecal microbiota transplants may lead to meaningful clinical response in certain UC patients.

- **Strategic collaboration with Nestlé Health Science (January 2016):** Seres granted Nestlé Health Science development and commercialization rights in global markets outside of the United States and Canada to SER-109 and SER-262 for CDI, and SER-287 and SER-301 for IBD. Seres has received an upfront payment of \$120 million and expects to receive an additional \$30 million in milestone payments in 2016. The full potential value of the upfront payment and milestone payments is over \$1.9 billion, assuming all products receive regulatory approval and are successfully commercialized. Seres is eligible to receive tiered royalties on sales ranging from the high single digit percentages up to the high teens for all products. Nestlé Health Science has also agreed to contribute to certain development efforts, including 33 percent of expenses for potential global Phase 3 studies for SER-287, SER-301 and SER-262. Seres intends to use capital obtained in the deal to drive continued pipeline growth and development. Seres continues to retain US and Canadian rights for all products, and global rights for all product candidates outside of CDI and IBD.
- **Commercial team leadership expansion (January 2016):** Wael Hashad has joined Seres as Chief Commercial Officer and Executive Vice President. Hashad is responsible for all activities related to the anticipated commercialization of the company's products in development. Hashad has 25 years of commercial leadership experience launching first- and best-in-class therapies at Amgen, Boehringer Ingelheim and Lilly.
- **Publication of SER-109 Phase 1b/2 clinical results (February 2016):** Positive results from the Phase 1b/2 study of SER-109 in recurrent CDI were published in *The Journal of Infectious Diseases*. In the study 87 percent of patients (26 of 30) met the predefined endpoint of preventing recurrent CDI within eight weeks following administration of SER-109, and 97 percent (29 of 30) achieved a clinical cure during the eight-week period after SER-109 dosing. The FDA has granted SER-109 Orphan Drug, as well as Breakthrough Therapy, designations.

Financial Results and Guidance:

The company reported a net loss of \$54.8 million for the full year, as compared to a net loss of \$18.0 million for the prior year. The company reported a net loss of \$19.6 million for the fourth quarter, as compared to a net loss of \$8.5 million for the fourth quarter of 2014. The increase in net loss was driven by clinical and development spending related to SER-109 and SER-287, continued growth in headcount, and ongoing development of our microbiome therapeutics platform, as well as increased facilities costs. The fourth quarter net loss included stock-based compensation expense of \$2.8 million as compared to \$1.4 million in the same period of the prior year.

Research and development expenses for the full year of 2015 were \$38.1 million, as compared to \$10.7 million for the prior year. Research and development expenses for the fourth quarter were \$13.9 million, as compared to \$5.1 million for the same period in the prior year. R&D expenses for the fourth quarter included stock-based compensation expense of \$1.5 million, as compared to \$0.7 million for the same period in the prior year.

General and administrative expenses for the full year were \$16.8 million, as compared to \$4.4 million for the prior year. General and administrative expenses for the fourth quarter were \$5.9 million, as compared to \$2.2 million for the same period in the prior year. The increase in G&A expense was due primarily to continued investment in business personnel and facility expansion to support overall growth, as well as increased professional fees, including those associated with the Nestle Health Science transaction, and costs associated with operating as a public company. G&A expenses for the quarter included stock-based compensation expense of \$1.3 million, as compared to \$0.6 million for the same period in the prior year.

Seres ended the third quarter of 2015 with \$219.3 million in cash, cash equivalents and investments and ended the fourth quarter with \$205.1 million in cash, cash equivalents and investments which does not include the \$120 million upfront payment received from Nestlé Health Science in February 2016.

During the fourth quarter of 2015, Seres signed an agreement to lease a facility that will house its corporate headquarters, including laboratories, office space, and a pilot manufacturing facility. The pilot facility will broaden capabilities in bioprocess development and synthetic microbiome candidate manufacturing. The company expects that build-out and equipment investment related to the facility will require approximately \$20 million of additional cash outlay during the first three quarters of 2016. Capital expenditures during the full year of 2015 totaled \$7.2 million including \$3.5 million incurred during the fourth quarter to support increased lab activities and expand internal manufacturing capabilities.

Based on the company's current operating plan, Seres expects that its existing cash resources will enable it to fund operating expenses and capital expenditure requirements, excluding cash inflows or outflows from business development activities, well into 2018.

About Seres Therapeutics

Seres Therapeutics, Inc. is a leading microbiome therapeutics platform company developing a novel class of biological drugs that are designed to treat disease by restoring the function of a dysbiotic microbiome characterized by an increased presence of pathogenic bacterial species, where the natural state of bacterial diversity is imbalanced. Seres' most advanced program, SER-109, has successfully completed a Phase 1b/2 study demonstrating a clinical benefit in patients with recurring *Clostridium difficile* infection (CDI) and is currently being evaluated in a Phase 2 study in recurring CDI. The FDA has granted SER-109 Orphan Drug, as well as Breakthrough Therapy, designations. Seres' second clinical candidate, SER-287, is being evaluated in a Phase 1b study in patients with mild-to-moderate ulcerative colitis.

Ecobiotic is a registered trademark of Seres. All other brand names, product names, trademarks or service marks belong to their respective holders.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the sufficiency of the company's existing cash resources, the commercialization of its CDI therapies, the timing of clinical trials and results from clinical trials, the value and impact of the agreement with Nestle Health Science and the Phase 1b/2 clinical study of SER-287, the sites, enrolled patients and evaluation criteria in the Phase 1b/2 clinical study of SER-287, dysbiosis of the microbiome as an underlying cause of UC, expected milestone payments under the agreement with Nestle Health Science and the use of capital from such agreement, expected uses of the company's new office, lab and manufacturing space and the expected increase in and timing of costs related to such space, and the potential impact of the pilot manufacturing facility.

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; 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 press release. Any such forward-looking statements represent management's estimates as of the date of this press release. 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 press release.

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SERES THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	<u>December 31,</u>	
	<u>2015</u>	<u>2014</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 73,933	\$ 114,185
Investments	131,149	—
Prepaid expenses and other current assets	2,528	58
Total current assets	<u>207,610</u>	<u>114,243</u>
Property and equipment, net	7,751	1,264
Restricted cash	1,539	139
Deferred offering costs	—	1,684
Deferred financing costs	—	15
Total assets	<u>\$216,900</u>	<u>\$ 117,345</u>
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 5,397	\$ 2,166
Accrued expenses and other current liabilities	5,523	1,737
Notes payable; current portion	—	1,200
Total current liabilities	<u>10,920</u>	<u>5,103</u>
Lease incentive obligation	586	—
Notes payable, net of discount	—	1,304
Preferred stock warrant liability	—	1,582
Total liabilities	<u>11,506</u>	<u>7,989</u>
Commitments and contingencies		
Convertible preferred stock (Series A, A-2, B, C, D and D-1), \$0.001 par value; 10,000,000 and 24,348,003 shares authorized at December 31, 2015 and 2014, respectively; 0 and 22,866,987 shares issued and outstanding at December 31, 2015 and 2014, respectively; aggregate liquidation preference of \$0 and \$137,283 at December 31, 2015 and 2014, respectively	—	136,077
Stockholders' equity (deficit):		
Common stock, \$0.001 par value; 200,000,000 and 38,000,000 shares authorized at December 31, 2015 and 2014, respectively; 39,082,017 and 6,890,250 shares issued and outstanding at December 31, 2015 and 2014, respectively	39	7
Additional paid-in capital	287,937	1,104
Accumulated other comprehensive income	30	—
Accumulated deficit	<u>(82,612)</u>	<u>(27,832)</u>
Total stockholders' equity (deficit)	<u>205,394</u>	<u>(26,721)</u>
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$216,900</u>	<u>\$ 117,345</u>

SERES THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year Ended December 31,		
	2015	2014	2013
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development expenses	\$ 38,095	\$ 10,718	\$ 4,805
General and administrative expenses	16,761	4,364	1,247
Total operating expenses	54,856	15,082	6,052
Loss from operations	(54,856)	(15,082)	(6,052)
Other income (expense):			
Interest income (expense), net	83	(209)	(42)
Revaluation of preferred stock warrant liability	(7)	(1,418)	(8)
Total other income (expense), net	76	(1,627)	(50)
Net loss	\$ (54,780)	(16,709)	(6,102)
Accretion of convertible preferred stock to redemption value	—	(1,291)	(875)
Net loss attributable to common stockholders	\$ (54,780)	\$ (18,000)	\$ (6,977)
Net loss per share attributable to common stockholders, basic and diluted	\$ (2.33)	\$ (2.67)	\$ (1.09)
Weighted average common shares outstanding, basic and diluted	23,532,400	6,748,037	6,394,916
Other comprehensive income (loss):			
Unrealized gain on investments, net of tax of \$0	30	—	—
Total other comprehensive income	30	—	—
Comprehensive loss	\$ (54,750)	\$ (18,000)	\$ (6,977)