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): April 6, 2022

SERES THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37465**	**27-4326290**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

200 Sidney Street **Cambridge, MA**	**02139**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 945-9626

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	**MCRB**	**The Nasdaq Stock Market LLC (Nasdaq Global Select Market)**

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 7.01. Regulation FD Disclosure.

On April 6, 2022, Seres Therapeutics, Inc. (the "Company") posted a slide presentation on its website at www.serestherapeutics.com. The presentation contains an updated pipeline reflecting the Company's decision not to proceed with the planned SER-301 Phase 1b second study cohort. The Company previously disclosed data obtained from the SER-301 Phase 1b first study cohort in the Company's Annual Report on Form 10-K filed on March 1, 2022 and in the corporate earnings call and press release issued that same day. The Company plans to continue research activities evaluating ulcerative colitis, including evaluating the potential to utilize biomarker-based patient selection and stratification for future studies. A copy of the slide presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is intended to be furnished and 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 set forth by specific reference in such filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

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 the Company's development plans in ulcerative colitis.

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 the Company's 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: the Company has incurred significant losses, is not currently profitable and may never become profitable; the Company's need for additional funding; the Company's limited operating history; the Company's unproven approach to therapeutic intervention; the lengthy, expensive, and uncertain process of clinical drug development; the Company's reliance on third parties to manufacture, develop, and commercialize its product candidates, if approved; the Company's ability to develop and commercialize its product candidates, if approved; the potential impact of the COVID-19 pandemic; the Company's ability to retain key personnel and to manage its growth; and that the Company's management and principal stockholders have the ability to control or significantly influence its business. These and other important factors discussed under the caption "Risk Factors" in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 1, 2022 and its 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 the Company may elect to update such forward-looking statements at some point in the future, the Company disclaims any obligation to do so, even if subsequent events cause its views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	Seres Therapeutics, Inc. Corporate Presentation as of April 6, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

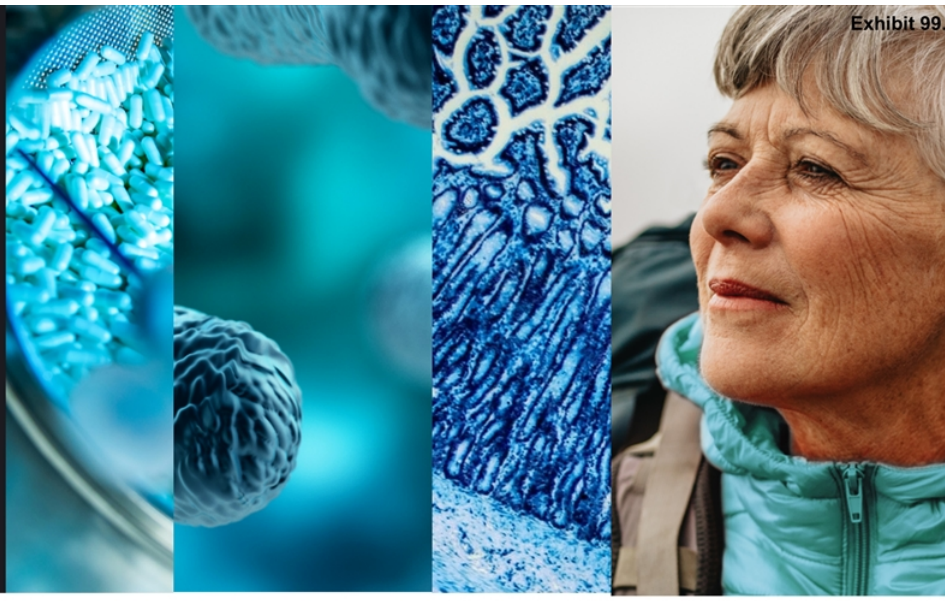
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SERES THERAPEUTICS, INC.

Date: April 6, 2022

By: /s/ Thomas J. DesRosier
Name: Thomas J. DesRosier
Title: Executive Vice President and Chief Legal Officer

SERES THERAPEUTICS



Corporate Overview

April 2022

Forward Looking Statements

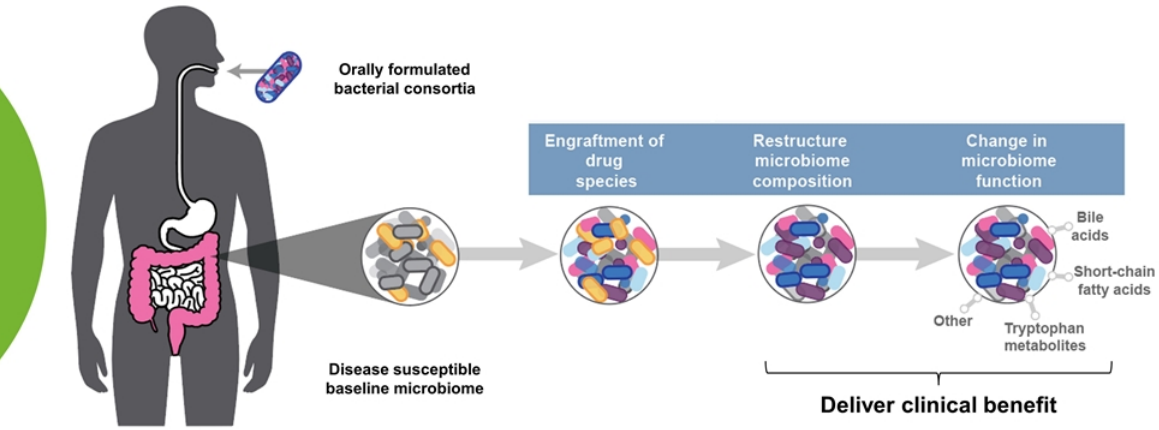
Some of the statements in this presentation constitute “forward looking statements” under the Private Securities Litigation Reform Act of 1995, including, but not limited to, the potential approval of SER-109 and its status as a first-in-class therapeutic, the timing of a BLA filing, the market for SER-109, and our capacity for commercial supply of SER-109; the anticipated indication and potential impact of Infection Protection microbiome therapeutics; plans, timing and potential impact of the release of additional preclinical and clinical data; our development opportunities and plans; the ultimate safety and efficacy data for our products; the potential of microbiome therapeutics to treat and prevent disease; the safety, efficacy and regulatory and clinical progress of our product candidates; the potential benefits of our collaborations; and other statements which are not historical fact. Such statements are subject to important factors, risks and uncertainties, such as those discussed under the caption "Risk Factors" in the Company’s Annual Report on Form 10-K filed on March 1, 2022, and its other filings with the SEC, that may cause actual results to differ materially from those expressed or implied by such forward looking statements. Any forward-looking statements included herein represent our views as of today only. We may update these statements, but we disclaim any obligation to do so.

SERES THERAPEUTICS™

Pioneering the Development of Microbiome Therapeutics

Seres' mission: To transform the lives of patients worldwide with revolutionary microbiome therapeutics

Encapsulated consortia of commensal bacteria designed to target multiple disease-relevant pathways simultaneously



Strategic Priorities

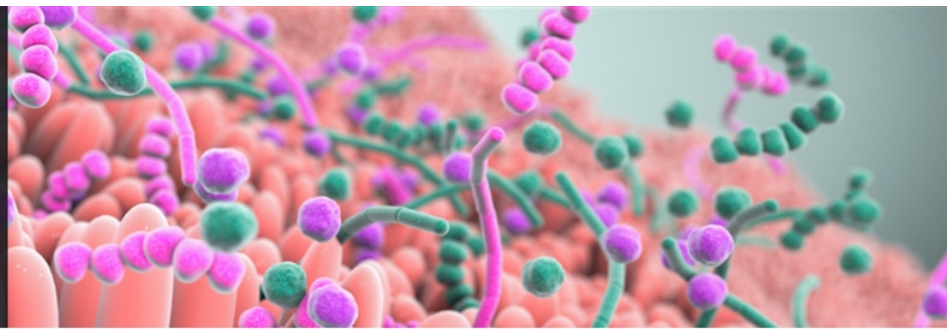
Bring first-in-class microbiome therapeutic to patients with **SER-109 BLA approval and successful launch** for recurrent CDI

Maximize opportunities in Infection Protection, based on proven mechanism of SER-109

Optimize plans for **continued development in UC** based on SER-287 and SER-301 trial data

SERES THERAPEUTICS

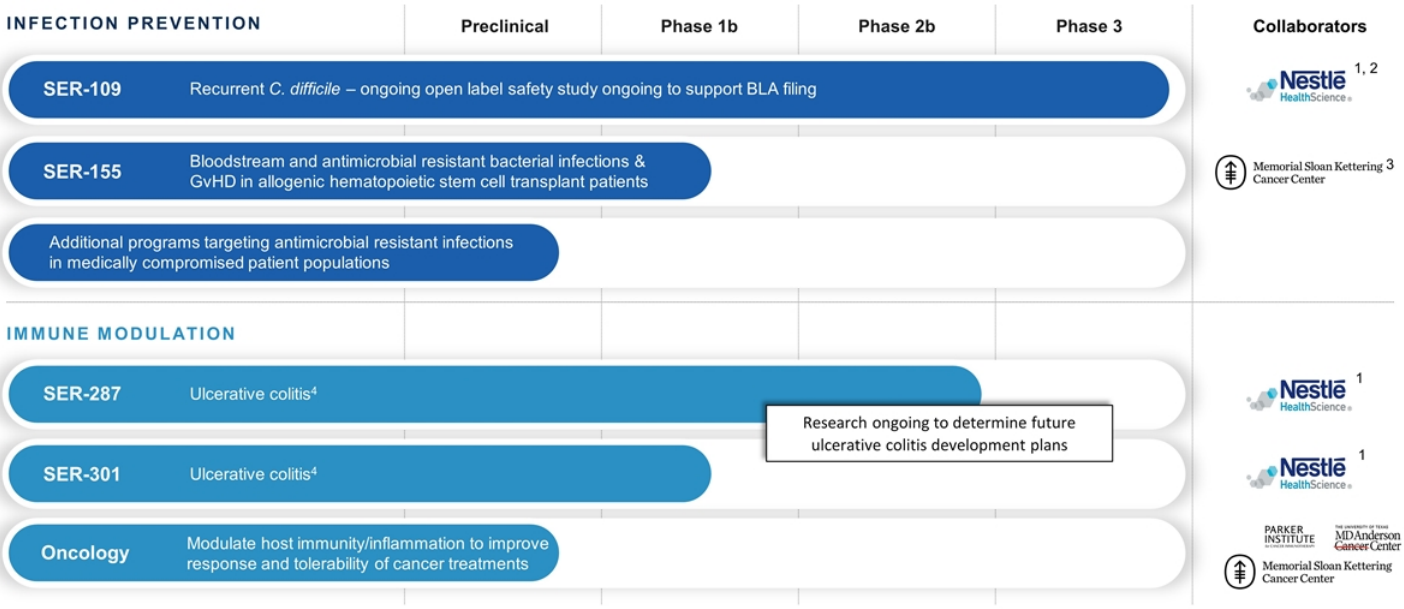
Expanding Microbiome Therapeutic Leadership in 2022+



- SER-109 **BLA filing in mid-2022;** potential to **transform management of recurrent *C. difficile* infection**
  - Preparing for commercial launch in collaboration with Nestlé Health Science
- Build on SER-109 by expanding into **additional opportunities in Infection Protection**
  - Explore SER-155 role in preventing infections and GvHD (Phase 1b ongoing)
- Determine **continued development in UC** based on SER-287 and SER-301 trial data
  - Clinical data suggest potential for biomarker-based patient selection

SERES THERAPEUTICS™

Broad Opportunities for Microbiome Therapeutics



1. Collaboration with Nestlé Health Science, announced Jan. 11, 2016, regarding *C. difficile* and IBD programs for markets outside of North America
2. SER-109 co-commercialization agreement for North America with Nestlé Health Science announced July 1, 2021
3. SER-155 preclinical work was supported in part by CARB-X
4. Translational research activities are ongoing, informed by learnings from SER-287 Phase 2b and SER-301 Phase 1b study data, to evaluate the potential to utilize biomarker-based patient selection and stratification in future clinical development efforts

SERES THERAPEUTICS™

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SERES THERAPEUTICS

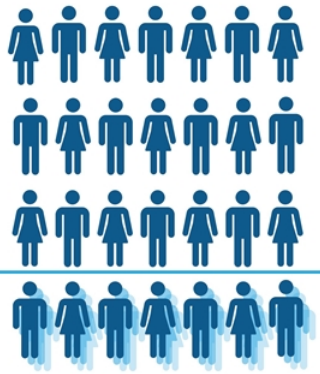
Substantial Recurrent *C. difficile* Infection Market Opportunity

SER-109

Infectious disease caused by toxin-producing bacteria, resulting in diarrhea, abdominal pain, fever and nausea

Leading cause of hospital-acquired infection in the U.S.

- ~453K cases of primary CDI within the U.S. each year
- ~170K episodes per year (100K episodes of first recurrence; ~ 70K episodes of 2+ recurrences)
- Estimated ~ $5B in healthcare burden each year
- Each rCDI patient results in ~$34,000 in direct healthcare expenses per year; substantial additional indirect costs



170,000
rCDI episodes per year

OVER

20,000
CDI deaths per year

25% patients facing recurrence

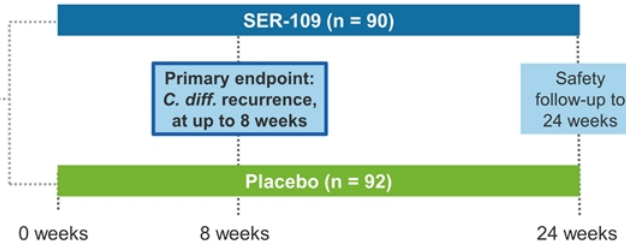
Sources: Desai et al., Epidemiological and economic burden of *Clostridium difficile* in the United States: estimates from a modeling approach, BMC Infectious Diseases (2016) 16:303; Guh AY et al. NEJM 2020

SERES THERAPEUTICS™

Highly Positive SER-109 Phase 3 Study Efficacy Results

TRIAL DESIGN

- Multiply recurrent *C. difficile* patients (n=182)
- All subjects treated with standard of care antibiotics



Approximately 88% sustained clinical response rate

Response rate far exceeded FDA predefined threshold for single pivotal trial

PRIMARY EFFICACY ENDPOINT RESULTS

Time point	SER-109 (N =89) n (%) of recurrences	Placebo (N =93) n (%) of recurrences	Relative risk (95%CI)	p-value (p1/p2)
Week 8	**11** (12.4)	**37** (39.8)	**0.32** (0.18-0.58)	**<0.001 / <0.001**

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Favorable Safety Profile Observed in Phase 3

- SER-109 was well tolerated, with no treatment-related serious adverse events (SAEs) observed in the active arm, and an **adverse event profile comparable to placebo**
- Overall incidence of patients who experienced AEs was similar between SER-109 and placebo arms throughout the study

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Phase 3 Data Published in New England Journal of Medicine

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

SER-109, an Oral Microbiome Therapy for Recurrent *Clostridioides difficile* Infection

Paul Feuerstadt, M.D., Thomas J. Louie, M.D., Bret Lashner, M.D., Elaine E.L. Wang, M.D., Liyang Diao, Ph.D., Jessica A. Bryant, Ph.D., Matthew Sims, M.D., Ph.D., Colleen S. Kraft, M.D., Stuart H. Cohen, M.D., Charles S. Berenson, M.D., Louis Y. Korman, M.D., Christopher B. Ford, Ph.D., Kevin D. Litcofsky, Ph.D., Mary-Jane Lombardo, Ph.D., Jennifer R. Wortman, M.Sc., Henry Wu, Ph.D., John G. Auniņš, Ph.D., Christopher W. J. McChalicher, B.Ch.E., Jonathan A. Winkler, Ph.D., Barbara H. McGovern, M.D., Michele Trucksis, M.D., Ph.D., Matthew R. Henn, Ph.D., and Lisa von Moltke, M.D.

ABSTRACT

BACKGROUND

Current therapies for recurrent *Clostridioides difficile* infection do not address the disrupted microbiome, which supports *C. difficile* spore germination into toxin-producing bacteria. SER-109 is an investigational microbiome therapeutic composed of purified Firmicutes spores for the treatment of recurrent *C. difficile* infection.

METHODS

We conducted a phase 3, double-blind, randomized, placebo-controlled trial in which patients who had had three or more episodes of *C. difficile* infection (inclusive of the qualifying acute episode) received SER-109 or placebo (four capsules daily for 3 days) after standard-of-care antibiotic treatment. The primary efficacy objective was to show superiority of SER-109 as compared with placebo in reducing the risk of *C. difficile* infection recurrence up to 8 weeks after treatment. Diagnosis by toxin testing was performed at trial entry, and randomization was stratified according to age and antibiotic agent received. Analyses of safety, microbiome engraftment, and metabolites were also performed.

RESULTS

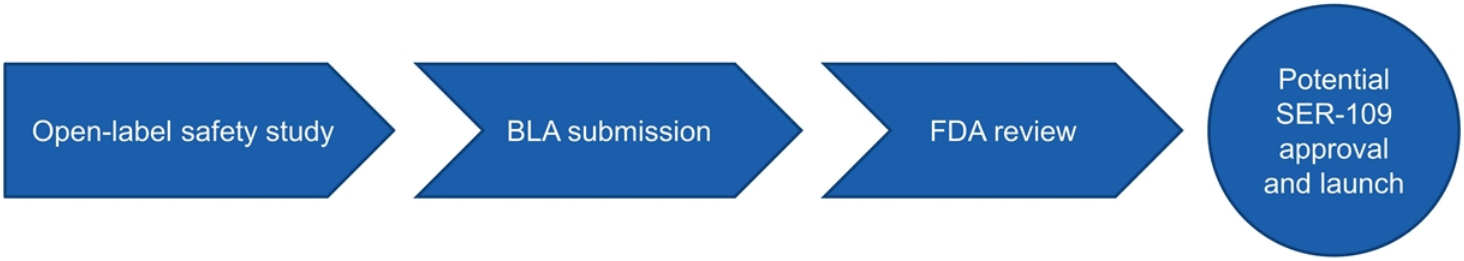
Among the 281 patients screened, 182 were enrolled. The percentage of patients with recurrence of *C. difficile* infection was 12% in the SER-109 group and 40% in

From Yale University School of Medicine, New Haven, and PACT Gastroenterology Center, Hamden — both in Connecticut (P.F.); the University of Calgary and Foothills Medical Centre, Calgary, AB, Canada (T.J.L.); Cleveland Clinic, Cleveland (B.L.); Seres Therapeutics, Cambridge, MA (E.E.L.W., L.D., J.A.B., C.B.F., M.-J.L., K.D.L., J.R.W., H.W., J.G.A., C.W.J.M., J.A.W., B.H.M., M.T., M.R.H., L.M.); Beaumont Hospital, Royal Oak, Royal Oak, and Oakland University William Beaumont School of Medicine, Rochester — both in Michigan (M.S.); Emory University, Atlanta (C.S.K.); the University of California, Davis, Davis (S.H.C.); the University at Buffalo and Veterans Affairs Western New York Healthcare System — both in Buffalo (C.S.B.); and Capital Digestive Care, Washington, DC (L.Y.K.). Dr. McGovern can be contacted at bmcgovern@serestherapeutics.com or at Seres Therapeutics, 200 Sidney St., Cambridge, MA 02139.

SERES THERAPEUTICS

On Track for BLA Submission in Mid-2022

SER-109



- Enrollment completed in September
- Study has 24-week follow-up period
- Study includes first and multiply recurrent patients

- BLA submission mid-2022 after study completion
- Expanded access program ongoing across multiple US sites

- Expect timely review in light of Breakthrough Therapy and Orphan Drug designations

SERES THERAPEUTICS

Well-Positioned to Meet Commercial Demand At Launch and Beyond

Seres In-house GMP manufacturing and quality control

Cell banking & inoculum

Drug substance

Drug product

Quality control

+

Bacthera collaboration provides redundancy and expands upon existing commercial supply capacity

BACTHERA

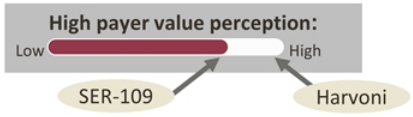
Joint venture between Chr. Hansen and Lonza with offices in Switzerland and Denmark

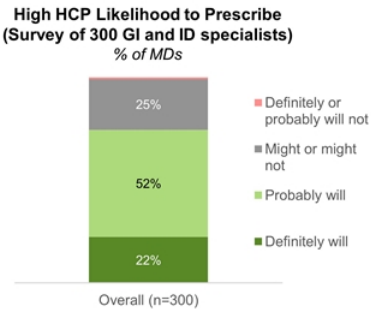
See Seres and Bacthera collaboration press release issued Nov. 10, 2021

SERES THERAPEUTICS

SER-109 is Potential First and Best-in-class Microbiome Therapeutic to Transform Care for Patients with rCDI

- **External stakeholder feedback on SER-109 is resoundingly positive**
  - Highly appealing addition to the current armamentarium for rCDI
  - Combination of efficacy and safety profile delivered in short 3-day oral regimen





- **SER-109 has potential to become the cornerstone of treatment**
- **Success is breaking the vicious cycle of recurrence that is the current hallmark of this disease**
  - Relieving patients of their fear and frustration
  - Providing HCPs for the first time a proven, highly effective option for sustained clinical response
  - Potentially transforming care for tens of thousands of patients across the US annually

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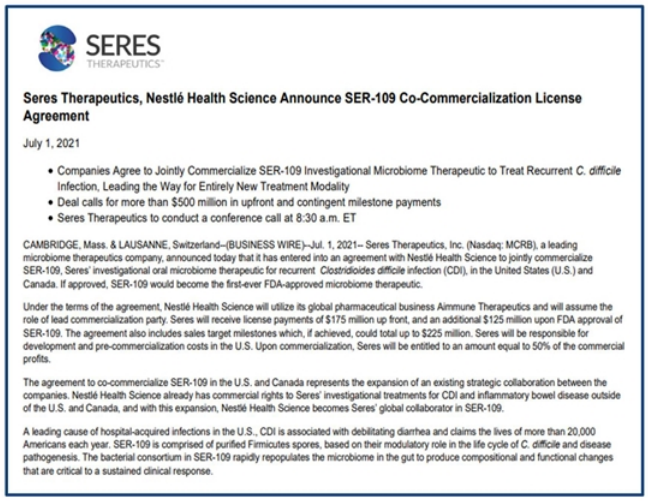
Seres, Nestlé Health Science SER-109 Co-Commercialization License Agreement for North America - Preparation for Launch

SER-109



SERES THERAPEUTICS

Seres Therapeutics, Nestlé Health Science Announce SER-109 Co-Commercialization License Agreement

July 1, 2021

- Companies Agree to Jointly Commercialize SER-109 Investigational Microbiome Therapeutic to Treat Recurrent *C. difficile* Infection, Leading the Way for Entirely New Treatment Modality
- Deal calls for more than $500 million in upfront and contingent milestone payments
- Seres Therapeutics to conduct a conference call at 8:30 a.m. ET

CAMBRIDGE, Mass. & LAUSANNE, Switzerland--(BUSINESS WIRE)--Jul. 1, 2021-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, announced today that it has entered into an agreement with Nestlé Health Science to jointly commercialize SER-109, Seres' investigational oral microbiome therapeutic for recurrent *Clostridioides difficile* infection (CDI), in the United States (U.S.) and Canada. If approved, SER-109 would become the first-ever FDA-approved microbiome therapeutic.

Under the terms of the agreement, Nestlé Health Science will utilize its global pharmaceutical business Aimmune Therapeutics and will assume the role of lead commercialization party. Seres will receive license payments of $175 million up front, and an additional $125 million upon FDA approval of SER-109. The agreement also includes sales target milestones which, if achieved, could total up to $225 million. Seres will be responsible for development and pre-commercialization costs in the U.S. Upon commercialization, Seres will be entitled to an amount equal to 50% of the commercial profits.

The agreement to co-commercialize SER-109 in the U.S. and Canada represents the expansion of an existing strategic collaboration between the companies. Nestlé Health Science already has commercial rights to Seres' investigational treatments for CDI and inflammatory bowel disease outside of the U.S. and Canada, and with this expansion, Nestlé Health Science becomes Seres' global collaborator in SER-109.

A leading cause of hospital-acquired infections in the U.S., CDI is associated with debilitating diarrhea and claims the lives of more than 20,000 Americans each year. SER-109 is comprised of purified Firmicutes spores, based on their modulatory role in the life cycle of *C. difficile* and disease pathogenesis. The bacterial consortium in SER-109 rapidly repopulates the microbiome in the gut to produce compositional and functional changes that are critical to a sustained clinical response.

Scaling Market Education Efforts

- Broadly engage KOL audience leveraging Seres and NHSc Medical Affairs teams
- Develop and deploy payer value proposition with NHSc payer account teams

Enhancing Understanding of Commercial Opportunity

- Conduct customer segmentation
- Identify options for go-to-market model
- Progress pricing analysis
- Determine patient engagement and support strategy

Building and Aligning Infrastructure to Launch

- Integrate activities across Seres and NHSc
- Hire next wave of key commercial roles across both companies

SERES THERAPEUTICS

Strategic Priorities

Bring first-in-class microbiome therapeutic to patients with **SER-109 BLA approval and successful launch** for recurrent CDI

Maximize opportunities in Infection Protection, based on proven mechanism of SER-109

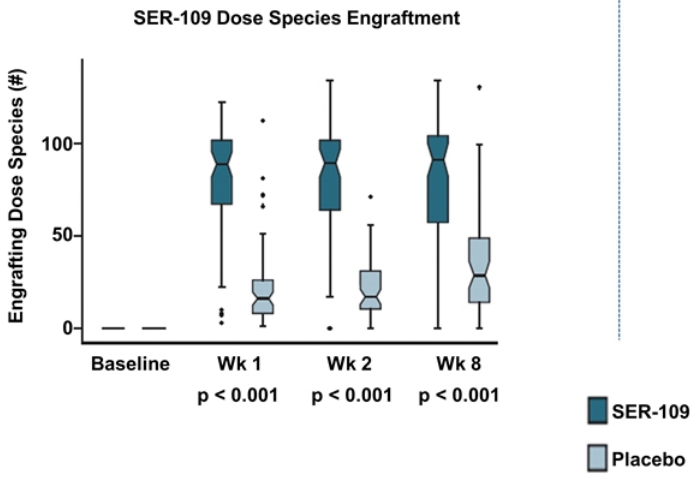
Optimize plans for **continued development in UC** based on SER-287 and SER-301 trial data

SERES THERAPEUTICS

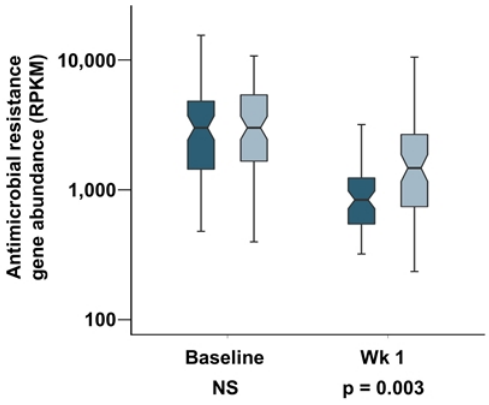
SER-109 Provides Proof of Concept - Restructuring the Microbiome and Reducing Pathogens

Infection Protection

SER-109 bacteria engraft durably & rapidly to restructure microbiome



Reduced antimicrobial resistance gene carriage



N = 182 patients enrolled; figure shows data for 143 patients at baseline
Feuerstadt P NEJM 2022; 386:220-9

SERES THERAPEUTICS

Antimicrobial Resistant Infections Are an Urgent Public Health Threat

Infection Protection

Major burden to society

World Health Organization

Declared "**one of the world's most urgent threats**"

CDC Centers for Disease Control and Prevention

$20 billion excess direct healthcare costs

35,000 deaths per year in the US

Many high risk patient populations

- **Allogeneic HSCT recipients** at risk for bloodstream infections
- Additional patients with **suppressed immune systems** (e.g., transplant recipients, cancer patients with neutropenia)
- Patients with **chronic diseases** (e.g., cirrhosis, type II diabetes)

Limited innovation despite substantial and growing impact

SERES THERAPEUTICS

SER-155 Phase 1b Study Ongoing

Infection Protection

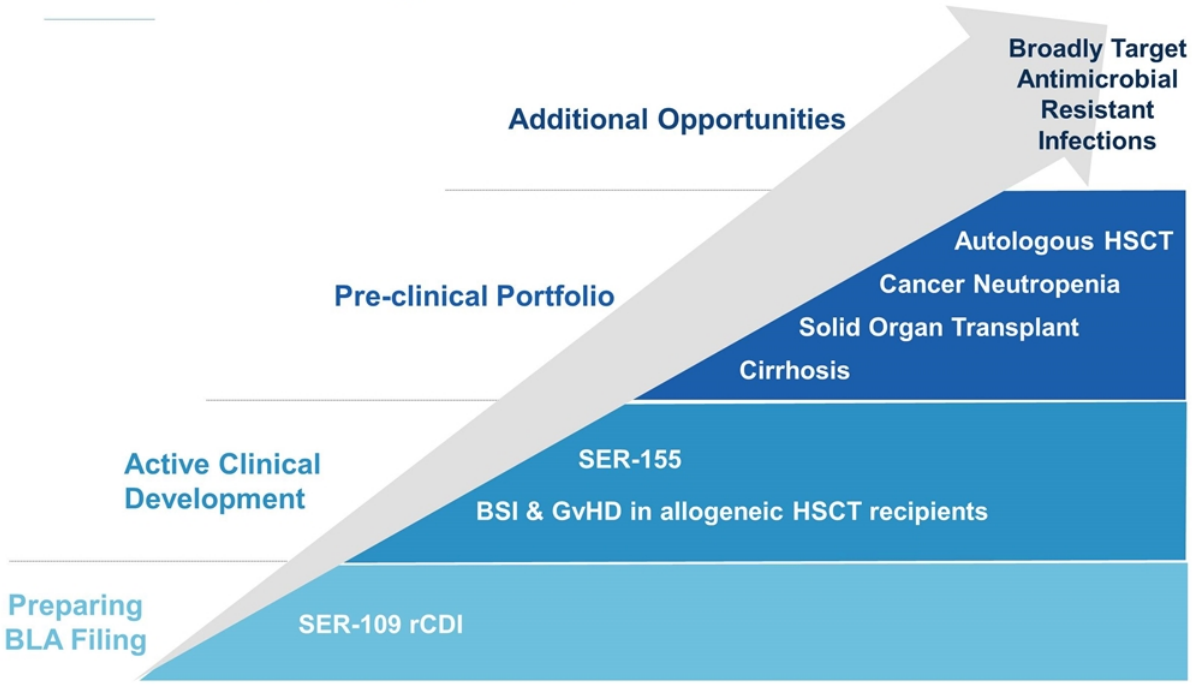
	SER-155
Microbiome drug type	Rationally designed, cultivated product; spore + vegetative species
Stage	Phase 1b - enrollment ongoing
Indication	Infection, bacteremia & GvHD in HSCT for cancer
Collaborations	Memorial Sloan Kettering Cancer Center

Phase 1b study design and objectives

- ~70 patients in an open-label and a randomized, double-blind, placebo-controlled cohort
- To evaluate safety and tolerability before and after allogeneic hematopoietic stem cell transplantation, as well as SER-155 engraftment bacteria and efficacy of SER-155 in preventing infections and GvHD

SERES THERAPEUTICS

Maximizing the Opportunity in Infection Protection and AMR



- Broad preclinical portfolio
- Driving to an **additional clinical development program in 2023**
- Potentially up to **3 additional programs within 3 years**

- Rich set of therapeutic adjacencies to *C. difficile*
- **SER-155 clinical development ongoing**

Strategic Priorities

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Maximize opportunities in Infection Protection, based on proven mechanism of SER-109

Optimize plans for **continued development in UC** based on SER-287 and SER-301 trial data

SERES THERAPEUTICS

Well-Capitalized to Extend Microbiome Therapeutic Leadership

SER-109 BLA approval and successful launch for recurrent CDI

SER-109: anticipate BLA filing in mid 2022

Opportunities in Infection Protection

SER-155: Phase 1b initiated and first patient enrolled

Preclinical programs ongoing

Continued development in UC

Ongoing research to inform plans for **continued development in UC**

As of Dec. 31, 2021: $291M in cash, cash equivalents and short and long-term investments

SERES THERAPEUTICS