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, 2023

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** **(Address of Principal Executive Offices)**	**02139** **(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 January 9, 2023, Seres Therapeutics, Inc. (the "Company") posted an updated corporate presentation in the "Investors and News" portion of its website at www.serestherapeutics.com. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following Exhibit 99.1 relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Exhibit Description
99.1	Seres Therapeutics, Inc. Corporate Presentation as of January 2023
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: January 9, 2023

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

SERES THERAPEUTICS

41st Annual J.P. Morgan Healthcare Conference

January 2023

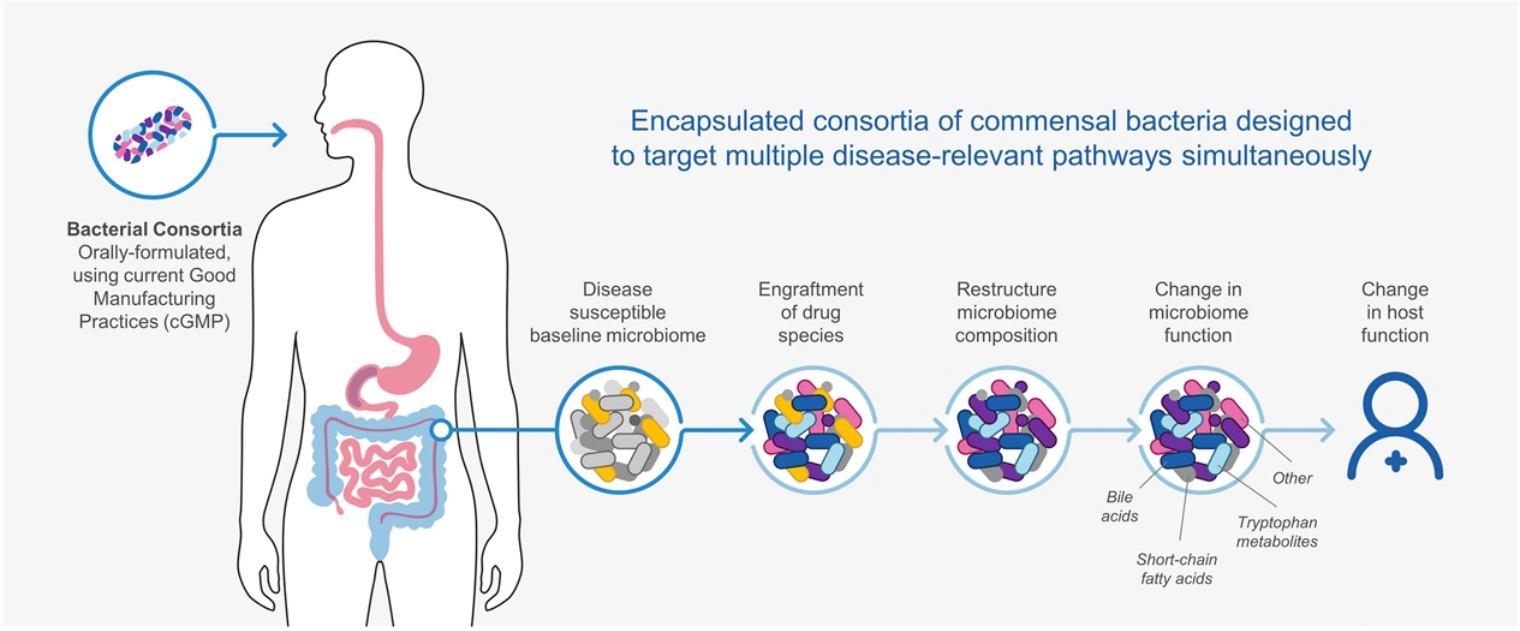
Eric Shaff, President and Chief Executive Officer

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 and launch of SER-109; the anticipated indication for SER-109; the anticipated supply of SER-109; the potential for microbiome therapeutics to protect against infection; the timing of clinical development; our development opportunities and plans; the ultimate safety and efficacy data for our products; the sufficiency of cash to fund operations; 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 Quarterly Report on Form 10-Q filed on Nov. 2, 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™

Seres Mission: Transforming the Lives of Patients Worldwide with Revolutionary Microbiome Therapeutics



SERES THERAPEUTICS

Strategic Priorities | Expanding Microbiome Therapeutic Leadership

Bring SER-109, potential first-in-class oral microbiome therapeutic, to recurrent CDI patients

- **SER-109 BLA submission complete**
- **PDUFA date April 26, 2023**
- **Anticipated launch soon after potential FDA approval**
- **Co-commercialization agreement with Nestlé Health Science**

Maximize opportunities in Infection Protection

- Phase 1b to explore SER-155 in preventing bacterial infections, including those caused by organisms that harbor antimicrobial resistance, in allo-HSCT patients, and GvHD
- DSMB clearance to SER-155 Phase 1b cohort 2, based on preplanned assessment of initial safety data
- Broad preclinical portfolio for medically compromised patients, including cancer neutropenia, cirrhosis and solid organ transplant

New update

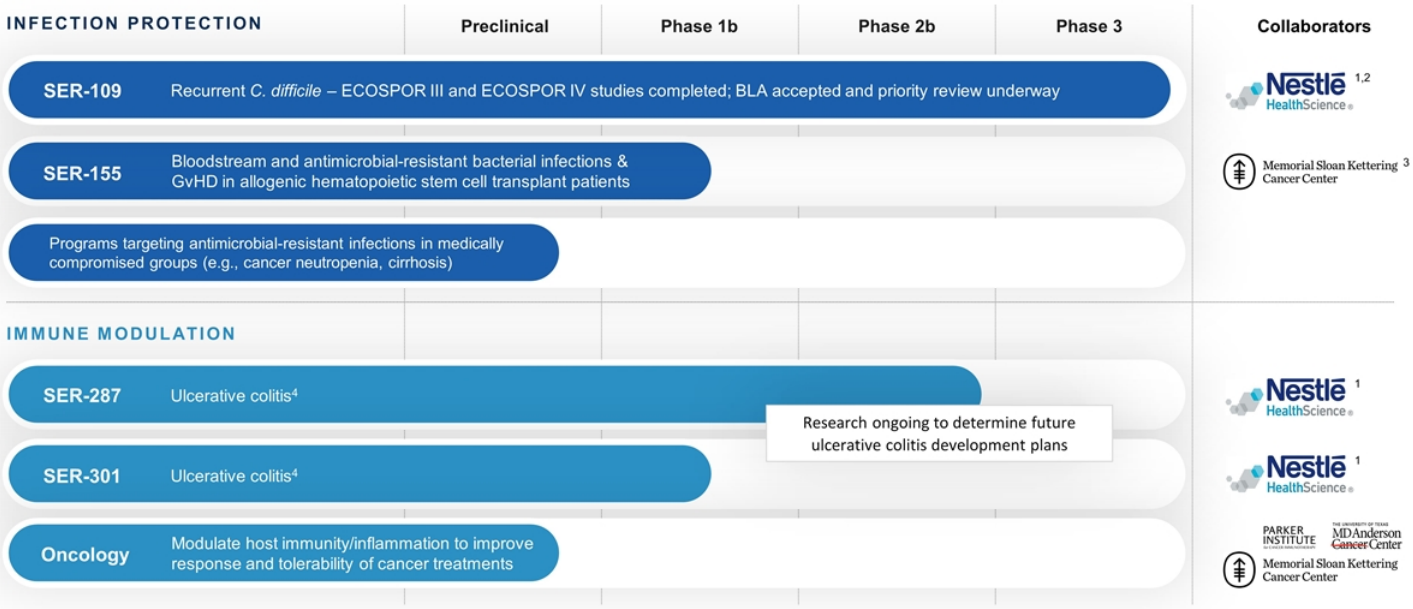
Continue research to inform further development in ulcerative colitis and immune modulation

- Potential for biomarker-based patient selection

SER-109 and SER-155 are investigational microbiome therapeutics that have not been approved by any regulatory authorities, including the U.S. Food and Drug Administration (FDA)

SERES THERAPEUTICS™

Corporate Priority is to Advance SER-109 to FDA Approval and Execute Successful Product Launch



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™

SER-109 and Recurrent *C. difficile* Infection

SERES THERAPEUTICS™

CDI – Urgent Public Health Threat

Spore-forming, toxin-producing, gram-positive, anaerobic bacteria

Symptoms include colitis and severe, watery diarrhea with **up to 15 bowel movements a day**

Acute onset of severe symptoms leads to **hospitalization** for many patients

High probability of recurrence >20%, usually within 1-2 weeks after completion of antibiotic therapy

~156K
Recurrent CDI cases estimated for 2023 (U.S.)

20,000+
CDI deaths per year (U.S.)

CLOSTRIDIOIDES DIFFICILE

THREAT LEVEL
URGENT

CDC

40-50%
Risk of recurrence escalates once a patient has an initial recurrence, trapping patients in a vicious cycle

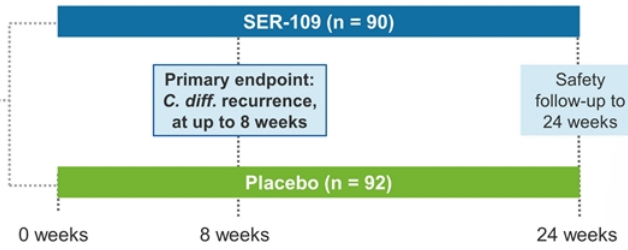
1. Centers for Disease Control and Prevention. *Antibiotic Resistance Threats in the United States, 2019.* US Department of Health and Human Services, CDC; 2019. doi:10.15620/cdc:82532 **2.** Feuerstadt P et al. *J Med Econ.* 2020;23(6):603-609. **3.** Chilton CH et al. *Clin Microbiol Infect.* 2017;24(5):476-482. **4.** Ofosu A. *Ann Gastroenterol.* 2016;29(2):147-154. **5.** Cole SA, Stahl TJ. *Clin Colon Rectal Surg.* 2015;28(2):65-69. doi:10.1055/s-0035-1547333. **6.** Wilcox MH et al. *Open Forum Infect Dis.* 2020;7(5):ofaa114. doi:10.1093/ofid/ofaa114 **7.** Centers for Disease Control and Prevention. Your risk of *C. diff*. Accessed January 28, 2022. https://www.cdc.gov/cdiff/risk.html **8.** Jiang ZD et al. *Aliment Pharmacol Ther.* 2017;45(7):899-908.**9.** McFarland LV et al. *Am J Gastroenterol.* 2002;97(7):1769-1775, https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecal-microbiota-product.

SERES THERAPEUTICS™

SER-109 ECOSPOR III Study Results

TRIAL DESIGN

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



Approximately **88%** **sustained clinical response rate***

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**

Note: Sustained clinical response % is calculated as 100% minus % with recurrence
* Compared to 60% in the placebo arm

SERES THERAPEUTICS™

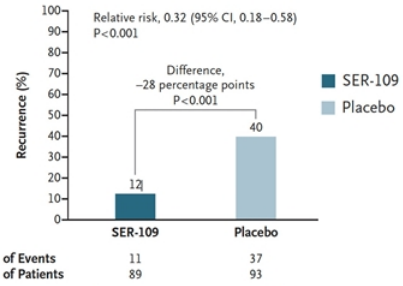
SER-109 Phase 3 Results Published in Premier Journals

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

Recurrence of C. difficile Infection up to 8 Weeks (Intention-to-Treat Population).



	SER-109	Placebo
No. of Events	11	37
No. of Patients	89	93

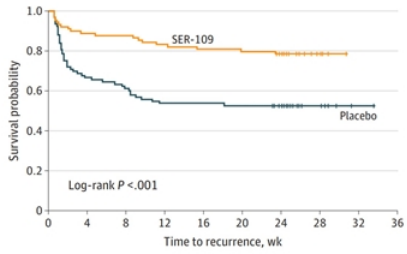
January 20, 2022

JAMA

RESEARCH LETTER

Extended Follow-up of Microbiome Therapeutic SER-109 Through 24 Weeks for Recurrent *Clostridioides difficile* infection in a Randomized Clinical Trial

Survival Function for Time to *Clostridioides difficile* Infection Recurrence



No. of patients at risk

Placebo	93	62	57	50	50	49	42	6	1
SER-109	89	79	78	74	72	71	62	4	0

October 19, 2022

SERES THERAPEUTICS

ECOSPOR III – Favorable Safety Profile Observed

Adverse Events (AEs) Through 8 Weeks (Safety Population)[2]	**SER-109 (n=90) n (%)**	**Placebo (n=92) n (%)**
Any adverse event	84 (93)	84 (91)
Adverse event related or possibly related to SER-109 or placebo	46 (51)	48 (52)
Serious adverse event[3]	7 (8)	15 (16)
Adverse event of special interest that occurred or worsened after initiation of SER-109 or placebo	1 (1)	1 (1)
Serious adverse event or an adverse event of special interest that occurred or worsened after initiation of SER-109 or placebo and was related or possibly related to SER-109 or placebo	0	0
Serious adverse event leading to withdrawal from the trial	0	1 (1)
Adverse event leading to death[4]	2 (2)	0

1. Feuerstadt P et al. *N Engl J Med*. 2022;386(3):220-229. **2.** Adverse events were coded with the use of the Medical Dictionary for Regulatory Activities, version 20.0. Adverse events of special interest included invasive infections such as bacteremia, meningitis, and abscess. **3.** Many of the serious adverse events were related to the primary endpoint of recurrent *C. difficile* infection, which was more common in the placebo group than in the SER-109 group. **4.** Three deaths occurred in the SER-109 group, all of which were reported by the investigator as being unrelated to SER-109; 2 of the participants had onset of fatal adverse events within the 8-week period after dosing, but only 1 of these 2 participants died during that period.

SERES THERAPEUTICS™

ECOSPOR IV Study (n=263) Results Extend ECOSPOR III Data

Overall safety profile through 24-week follow up:

SER-109 was well tolerated, consistent with profile observed in ECOSPOR III

Sustained clinical response rate:

91%

similar to 88% rate observed in ECOSPOR III

Sustained clinical response rate in patients with first recurrence:

94%

Seres believes that based on disease pathophysiology and overall Phase 3 results, SER-109 may provide clinical benefit across entire recurrent CDI patient population

SERES THERAPEUTICS

Note: Company announced ECOSPOR IV results on June 7, 2022

Delivering SER-109 to Patients; PDUFA Date April 26, 2023

We are here

BLA submission

- BLA submission completed Q3 2022; acceptance confirmed by FDA Oct. 2022
- Expanded access program ongoing across multiple US sites

Priority FDA review

- Accelerated review based on Breakthrough Therapy Designation
- Orphan Drug Designation

Potential SER-109 approval and launch

- PDUFA date April 26, 2023

SERES THERAPEUTICS

SER-109 May Fill an Important Unmet Need – Prevention of Recurrence

- Early and urgent intervention in the cycle of recurrence can prevent further recurrences
- SER-109 could have a unique place in the treatment algorithm, potentially transforming standard of care:
  - Reducing the need for antibiotic taper regimens and other options that do not restore the microbiome and break the cycle
  - Reducing repeated short course regimens of antibiotics alone, without subsequent microbiome restoration
  - Attractive value proposition compared to FMT-based approaches

If approved, SER-109 may serve as appropriate foundational therapy for a broad set of patients caught in the vicious cycle of recurrence

- ✓ **Demonstrated efficacy**
- ✓ **Attractive safety profile**
- ✓ **Convenient route of administration**

SERES THERAPEUTICS™

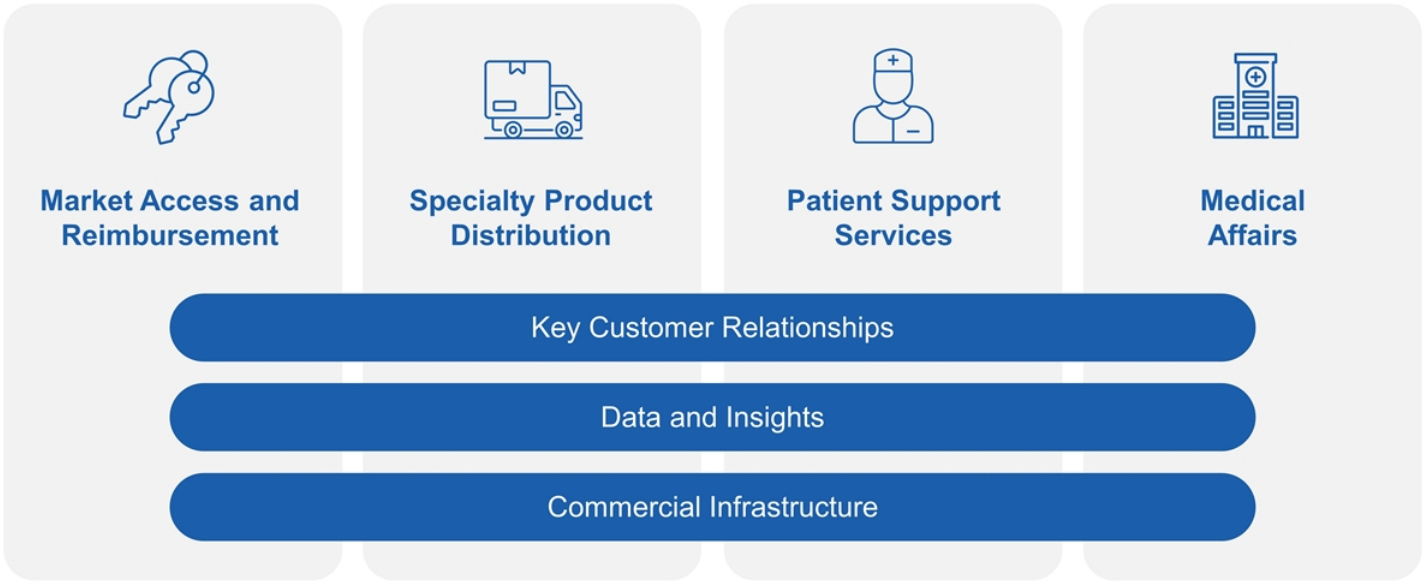
Well Positioned for Commercial Success

1. Highly Favorable Product Profile, Pending Approval
2. Substantial Market Opportunity
3. Commercial Capabilities, Including Manufacturing

Preparing for successful SER-109 commercial launch alongside collaborator, Nestlé Health Science

Seres press release issued on July 1, 2021, to announce U.S. Co-commercialization license agreement with Nestlé Health Science

Seres and Nestlé Health Science have Full Suite of Resources and Complementary Capabilities to Support SER-109 Launch



Focusing on the Most Important Areas at Launch to Set Up SER-109 for Long Term Success if Approved

	LAND First 12 months	EXPAND >12 months
Patient Access	• Implement payer policies as quickly as possible to ease access to treatment • Access programs to support positive early experience • Ensure high quality HUB and partner support for patients	• Optimize patient support offerings • Continue to address remaining access barriers
Product Choice	• Focus awareness and education efforts on highest volume HCPs • Establish supportive ecosystems in high volume hospitals • Patient activation strategies focused on highly engaged patients	• Expand demand generation efforts • Broaden patient activation efforts

SERES THERAPEUTICS™

Well Positioned to Supply Commercial Demand at Launch and Beyond

10+ years of Investment in Technology and Facilities for anaerobic bacterial therapeutics:

- **In-house GMP Manufacturing and Quality Control**
- **Supported by high-quality CMOs: Recipharm, PCI**



+

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*

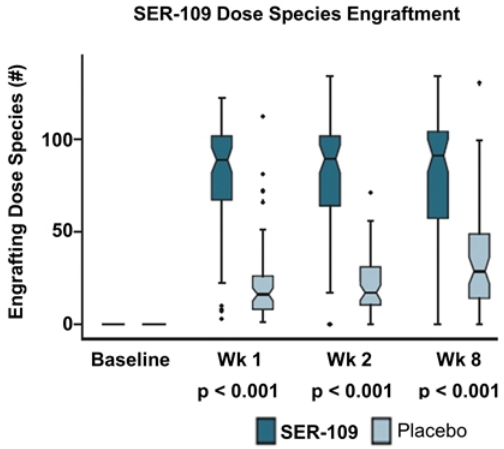
Note: Seres and Bacthera collaboration press release issued Nov. 10, 2021

SER-155 and Infection Protection Franchise

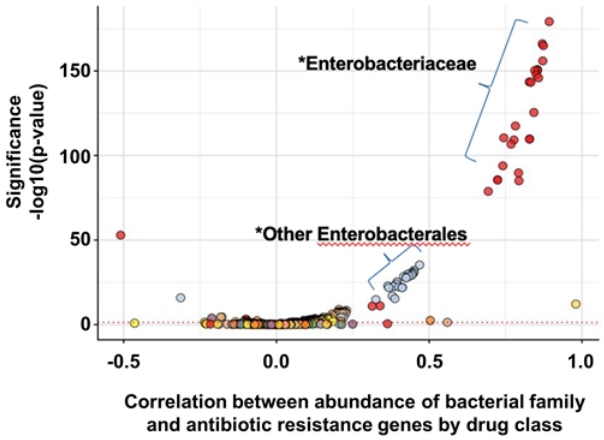
SERES THERAPEUTICS™

SER-109 Clinical Data Provide Proof of Concept - Restructuring the Microbiome and Reducing Pathogens

SER-109 bacteria engraft durably & rapidly to restructure microbiome



Engraftment reduces proteobacteria* associated with antimicrobial resistance genes



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

SERES THERAPEUTICS

Antimicrobial Resistant Infections - Urgent Public Health Threat

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 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)
- Patients with **chronic diseases** (e.g., cirrhosis)

Limited innovation despite substantial and growing impact

SERES THERAPEUTICS

Potential Novel Approach to Address Infection - SER-155 Phase 1b Study Ongoing

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

Phase 1b study design and objectives

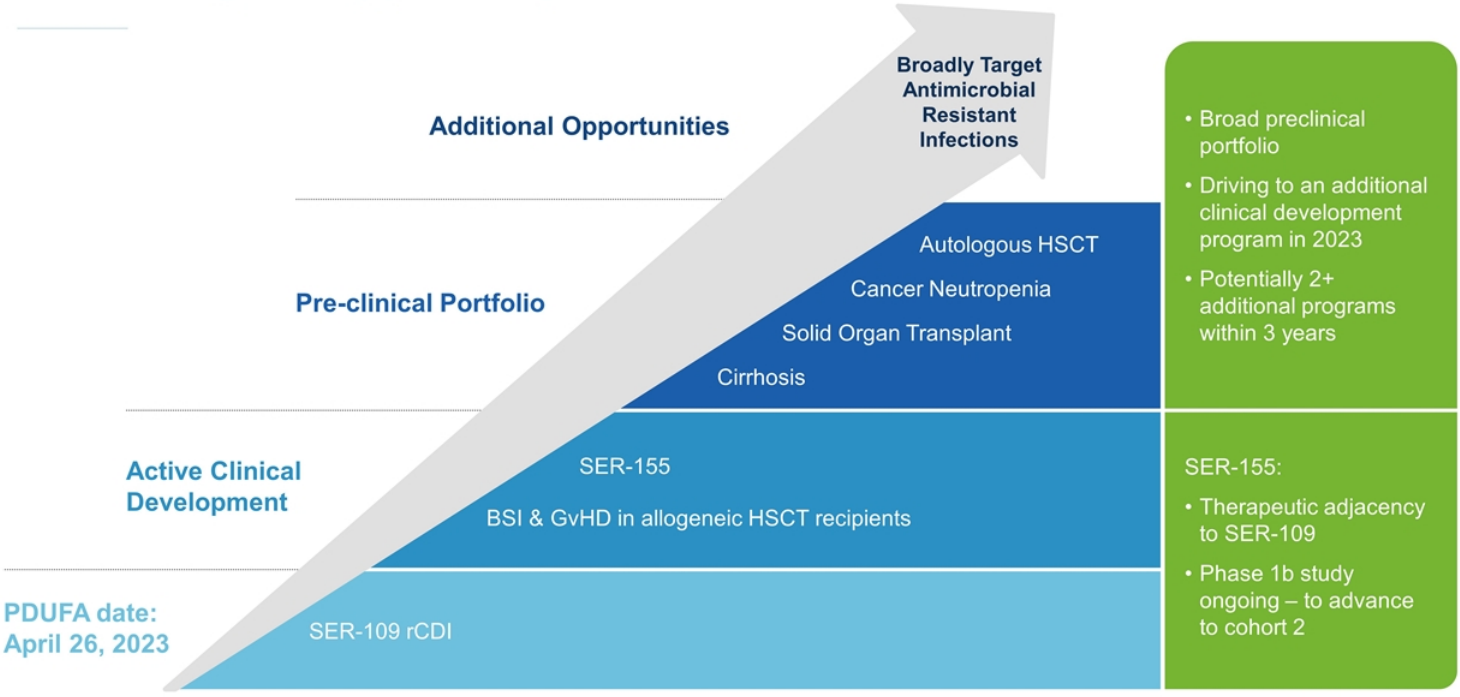
~70 patients in an open-label and a randomized, double-blind, placebo-controlled cohort

- 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

- **Based on pre-planned review of safety data with DMSB in Dec. 2022, study to advance to cohort 2**
- **Initial safety and pharmacological data expected in early 2023**

SERES THERAPEUTICS

Maximizing the Opportunity in Infection Protection and AMR



SERES THERAPEUTICS

Well Positioned to Extend Microbiome Therapeutic Leadership in 2023

Potential SER-109 BLA approval and successful launch for rCDI

- BLA submission complete; FDA PDUFA target action date of April 26, 2023
- Working closely with Nestlé to prepare for commercial launch
- Producing supply to support commercial demand
- $125M milestone payment anticipated from Nestlé upon FDA approval

Opportunities in Infection Protection

- SER-155 Phase 1b ongoing; initial safety and pharmacological data in early 2023
- Preclinical programs ongoing with potential to address large immunocompromised patient populations

Continued research in UC and microbiome therapeutic platform

- Ongoing research to inform plans for continued development in UC
- Extend industry-leading microbiome therapeutic platform capabilities

Sept. 30, 2022 cash balance of approximately:

$233 million

SERES THERAPEUTICS™

Continued Microbiome Therapeutic Leadership, Anticipated Compelling Growth and Value Creation

2023

Potential SER-109 BLA approval and successful launch for rCDI

Advancing opportunities in Infection Protection and other therapeutic areas

2025

- If approved, SER-109 transforming standard of care for a broad population of rCDI patients
- SER-155 in late-stage clinical development
- 2+ additional Infection Protection candidates in clinical development
- Extend industry-leading microbiome therapeutic platform

SERES THERAPEUTICS