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 31, 2017

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

Delaware	**001-37465**	**27-4326290**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

200 Sidney Street
Cambridge, MA 02139
(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 7.01. Regulation FD Disclosure.

On January 31, 2017, Seres Therapeutics, Inc. (the "Company") will host an investor conference call and live webcast to present the results of its in-depth analyses of the previously reported SER-109 Phase 2, 8-week clinical study data in patients with multiply recurrent *Clostridium difficile* infection. A copy of the slide presentation from this conference call is attached as Exhibit 99.1 to this Current Report on Form 8-K. The slide presentation will be archived for approximately 30 days in the "Investors & Media" portion of the Company's website at www.serestherapeutics.com.

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.

Exhibit No.	Exhibit Description
99.1	SER-109 Phase 2 Study Analysis Slide Deck for Presentation on January 31, 2017

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 31, 2017

By: /s/ Eric D. Shaff
Name: Eric D. Shaff
Title: Executive Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Exhibit Description
99.1	SER-109 Phase 2 Study Analysis Slide Deck for Presentation on January 31, 2017

Exhibit 99.1

Key Findings from SER-109 Phase 2 Study Analyses

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Leading the Microbiome Revolution

January 31, 2017

Forward looking statements

Some of the statements in this presentation constitute “forward looking statements” under the Private Securities Litigation Reform Act of 1995. Such statements are subject to factors, risks and uncertainties (such as those detailed in the Company’s periodic filings with the SEC) that may cause actual results to differ materially from those expressed or implied by such forward looking statements.

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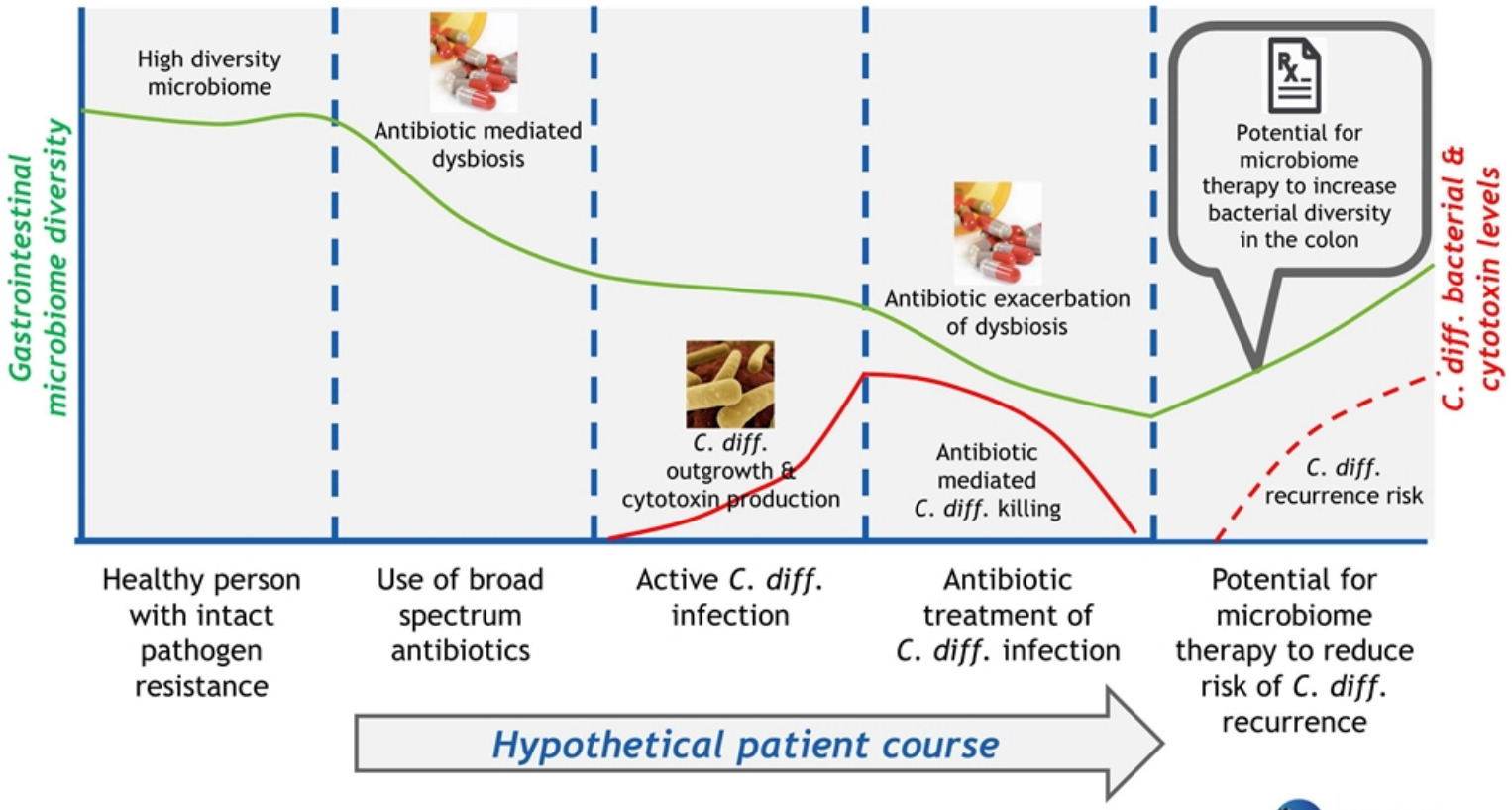
Microbiome dysbiosis and potential for therapeutic intervention



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SER-109 overview

- Lead product candidate, completed Phase 2 study in patients with recurrent *C. difficile* infection
- Oral, biologically sourced, spore based therapeutic candidate
- Intended to catalyze an increase in the diversity of commensal microbes to repair a dysbiotic, disease state microbiome
- Therapeutic objective: Reestablish colonization resistance, and reduce the risk of further recurrences of *C. difficile* infection

SER-109 capsules

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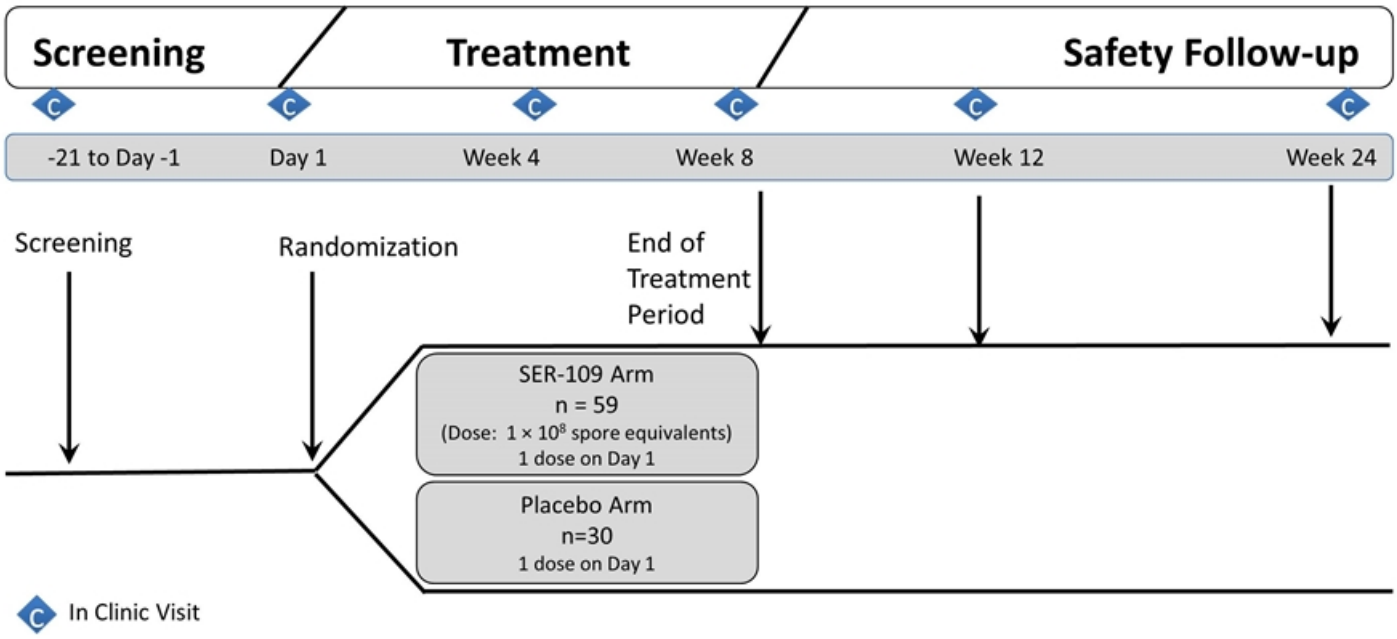
SER-109 Phase 2 ECOSPOR study overview



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SER-109 Phase 1b and Phase 2 (8-week) study results

	Phase 1b Open Label, Single-Arm (n=30; 4 sites)	Phase 2 – Interim results Randomized, Placebo-Controlled (n=89; randomized 2:1; 28 sites)
Primary Endpoint	CDI recurrence up to 8 weeks defined by: >3 unformed stools over 1 day	CDI recurrence up to 8 weeks defined by: ≥3 unformed stools/day for ≥2 days
Efficacy	• 13% recurrence per protocol • 3 of 4 patients with recurrent transient diarrhea, did not require antibiotic treatment and tested negative for C. difficile at 8 weeks	• SER-109: 44% (26 of 59) recurrence • Placebo: 53% (16 of 30) recurrence • Relative risk recurrence between arms not significant • ≥65 and <65 years of age had differential results
Safety	• Most AEs were mild to moderate and transient • Most frequent AEs were gastrointestinal symptoms similar in nature to that seen in FMT trials or following CDI	• SER-109 is well-tolerated with an acceptable safety profile, it was associated with a small increase in gastrointestinal adverse effects, particularly diarrhea, compared to placebo (25% vs 14%)

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Comparison of SER-109 Phase 1b and Phase 2 studies

	Parameter	Phase 1b	Phase 2
Study Design	Overview	Open label; investigator sponsored; 4 sites; n=30	Placebo controlled randomized 2:1 SER-109:placebo; 28 sites enrolled subjects, n=89
	Endpoint	• CDI recurrence at up to 8 weeks defined by: • ≥ 3 unformed stools over 1 day • Positive *C. difficile* stool test (PCR or ELISA toxin assay)	• CDI recurrence at up to 8 weeks defined by: • > 3 unformed stools/day over 2 or more days • Positive *C. difficile* stool test (PCR or ELISA toxin assay) • Assessment by investigator that antibiotic is required
	Stratification	No prespecified stratification	<65 years old and ≥65 years old
	Antibiotics use prior to randomization	CDI antibiotic type selected by investigator; any duration	10 to 21 days, limited to vancomycin or fidaxomicin
	Inclusion criteria: Prior CDI recurrences	• ≥ 3 CDI episodes within 12 months, inclusive of current episode	• ≥ 3 CDI episodes within 9 months, inclusive of current episode
	Timing of SER-109 / PBO relative to antibiotic use	2 day post stopping antibiotics	2-4 days post stopping antibiotics
	Dose	Variable, from 3 X 10^7 to 2 X 10^9 spore equivalents Cohort 1 (n=15): 30 capsules over 2 days; Cohort 2 (n=15): 1-7 caps over 1 day	1 X 10^8 spore equivalents 4 capsules over 1 day
Study Demographics	Median prior recurrences	3 (2 to 6 range)	3 (2 to 7 range)
	Average age	61.9	64.5
	% Female	67%	67%
Drug Product	Manufacturing process	• Drug lots based on material from 7 donors	• Drug lots based on material from 3 new donors • Additional purification steps added to increase spore purity
	Formulation	• 1 to 30 capsules depending on spore concentration, desired dose	• 4 capsules, modified to facilitate automated fill

Note: Selected parameters

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SER-109 Phase 2 24-week study results

- Phase 2 efficacy results
  - 5 additional patients recurred after the 8 week primary endpoint in the SER-109 arm but 3/5 (60%) were patients who terminated the trial early (i.e., lost to follow-up - imputed recurrences)
  - 1 additional patient recurred in the placebo arm; this patient also terminated the trial early and was lost to follow-up
- Phase 2 safety results
  - SER-109 was generally well tolerated
  - The most common SER-109 treatment arm adverse events included diarrhea and abdominal pain
  - SER-109 may result in mild GI symptoms, as noted with fecal microbiota transplantation
  - Severe adverse event rate (15.0% for SER-109, 10.3% for placebo)
    - No SAEs were classified as drug related

Note: In study recurrences were diagnosed based on various *C. difficile* testing methodologies (i.e., PCR, GDH, cytotoxin)

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SER-109 Phase 2 open label extension study results

- Open label extension (OLE) study (SERES-005) design:
  - Phase 2 subjects who experienced a *C. difficile* recurrence in the first 8 weeks following drug administration had the option to enroll in the 24-week OLE study to assess safety and efficacy
  - Same SER-109 regimen as Phase 2 study (i.e., SER-109 treatment following antibiotic course to treat acute *C. difficile* recurrence)
  - 34 subjects entered the OLE study (21 from SER-109 arm; 13 from placebo arm)
- Study results:
  - SER-109 was found to be generally well tolerated. The most common AEs observed were diarrhea and abdominal pain
  - Recurrences in the OLE study: 11/34 overall (68% non-recurrence)

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SER-109 Analyses & Findings

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Organization of SER-109 study analyses

Analysis component	Key issues addressed
Clinical	• Detailed analyses of clinical data • Investigation of *C. difficile* diagnostics
Pharmacodynamics / microbiome analyses	• Investigation of drug activity
Chemistry, Manufacturing and Controls (CMC)	• Drug product distribution and handling • Phase 1b to Phase 2 manufacturing and formulation changes, and potential impact on drug activity

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Comparison of common *C. difficile* diagnostic tests

Test	Basis of test	Comments
PCR	• Detects genes encoding cytotoxins • Most sensitive test • Does not distinguish *C. difficile* carriage from active infection	• Most common test in U.S. • Used for 80.9% of entry tests and 74% of exit tests in Phase 2 study
EIA GDH	• Enzyme immunoassay for GDH, an essential *C. difficile* protein • Does not distinguish *C. difficile* carriage from active infection	• Only used in conjunction with EIA cytotoxin test • Increases specificity of cytotoxin test
EIA Cytotoxin	• Enzyme immunoassay for cytotoxin • Detects both cytotoxins A and B • Less sensitive than PCR	• Cytotoxin protein is the signature of an active infection

Misdiagnosis of *C. difficile* carriage as infection could impact both: 1) inclusion of the proper patient population, and 2) accurate measurement of the study endpoint

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Analysis of *C. difficile* diagnostic test: Qualifying episode

- PCR was the most common method used to qualify patients for enrollment into Phase 2 study: 72 of 89 (80.9%) subjects were diagnosed by PCR
  - Qualifying Phase 2 stool samples were not available for re-testing by Cytotoxin EIA
- Available stool samples that qualified subjects for the open label extension study were re-tested to examine the hypothesis that PCR diagnostics may have enabled inclusion of non-eligible subjects:
  - Of the 34 subjects entering the open label extension study, 31 were re-tested
  - 15/31 (44%) tested positive by cytotoxin either on study or at retest (16/31 subjects who tested positive by PCR did not test positive by cytotoxin)

- Applying this information to the Phase 2 study, some subjects may have entered the study without recurrent *C. difficile* infection
- Inclusion of misdiagnosed patients may have reduced Phase 2 study power, and complicated the interpretation of study results

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Analysis of *C. difficile* diagnostic test: Phase 2 recurrence endpoint results

- 32 of 42 (76%) of Phase 2 stool samples associated with a presumed recurrence were available to be analyzed by re-testing for cytotoxin by an independent laboratory

	Testing laboratory results				
	Placebo		SER-109		RR (95% CI)
Source of Recurrence C. *difficile* Test Results	n	Number with Recurrence (%)	n	Number with Recurrence (%)	
On Study (all test methods)	30	16 (53.3%)	59	26 (44.1%)	1.22 (0.79, 1.88)
Re-Test Results: Recurrence results based only on positive cytotoxin test, either on study or at re-test (i.e., high confidence recurrences)	21	7 (33.3%)	44	11 (25.0%)	1.46 (0.71, 3.03)

Note: Dataset demonstrates the Phase 2 endpoint *C. diff.* diagnostic results, and includes a portion of the dataset described on slide 13

Use of PCR to measure *C. difficile* recurrences may have overestimated study recurrences in both treatment arms as it does not identify clinical disease, and further complicated interpretation of Phase 2 study results

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SER-109 Microbiome Response & CMC Analyses

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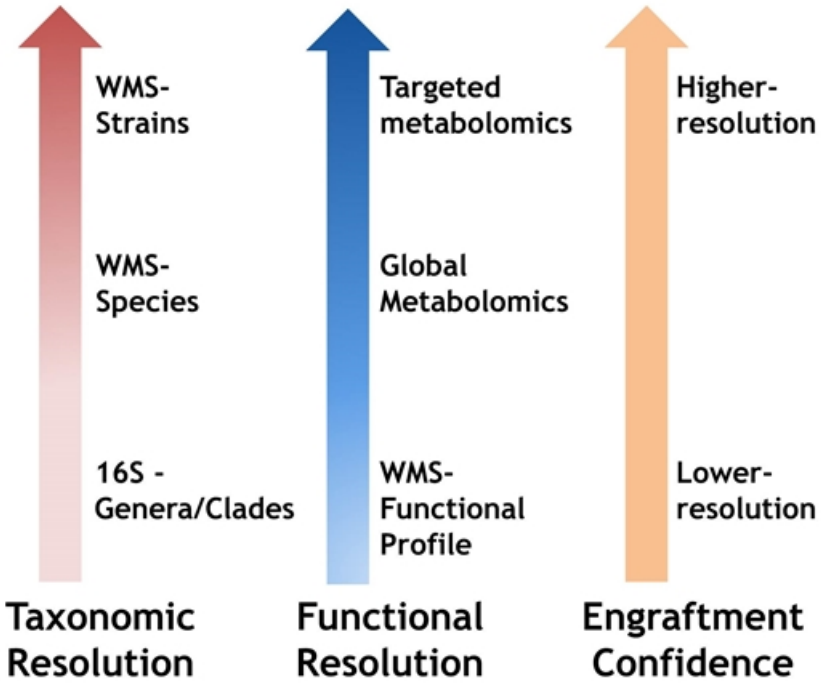
Seres microbiome platforms

- Microbiome dynamics interrogated using genomic, metabolomic, and microbiology platforms
- Genomic tools leverage 16S ribosomal gene sequencing, and Whole Metagenomic Sequencing (WMS) data types
- Metabolomic tools leverage broad global profiling and targeted functional data for specific metabolic pathways
- As part of the Phase 2 analyses, tools & algorithms to assess microbiome pharmacokinetics & pharmacodynamics at high-resolution have been refined:
  - Developed novel computational approaches to detect & model engraftment of specific species & strains using WMS data
  - Broadened functional profiling capabilities to model microbiome dynamics; developed novel algorithms for high-resolution, integrated analysis of WMS and metabolomic data sets



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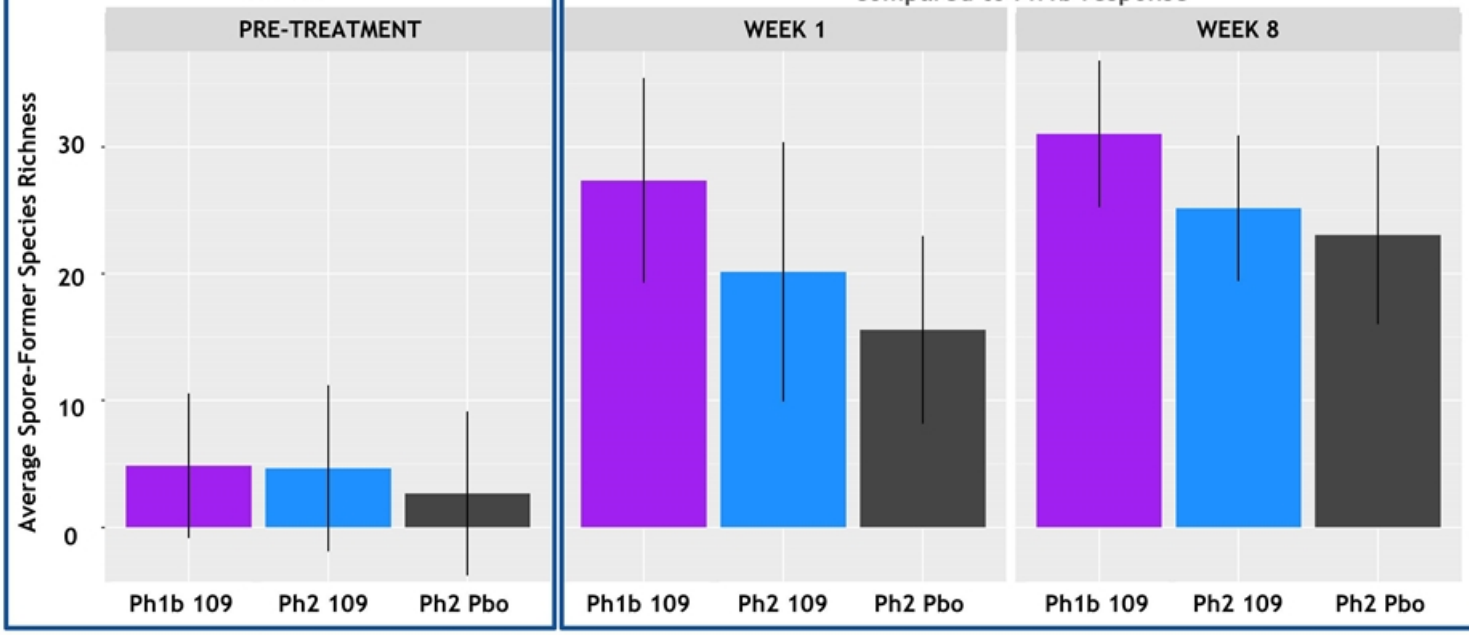
SER-109 treatment demonstrates increased microbiome diversity

Comparable dysbiosis in commensal spore-former bacterial diversity in Ph1b & Ph2 subjects prior to treatment

Dysbiotic microbiome is on average 5 fold lower diversity than Human Microbiome Project healthy controls

Demonstrated in Ph2 an increase in diversity of commensal spore-former bacteria with significantly greater response in SER-109 vs Pbo at Week 1

Ph2 increase in commensal spore-former bacteria is significantly less robust at Weeks 1 & 8, and achieved maximum change more slowly as compared to Ph1b response



Note: Data reported as mean ± standard deviation

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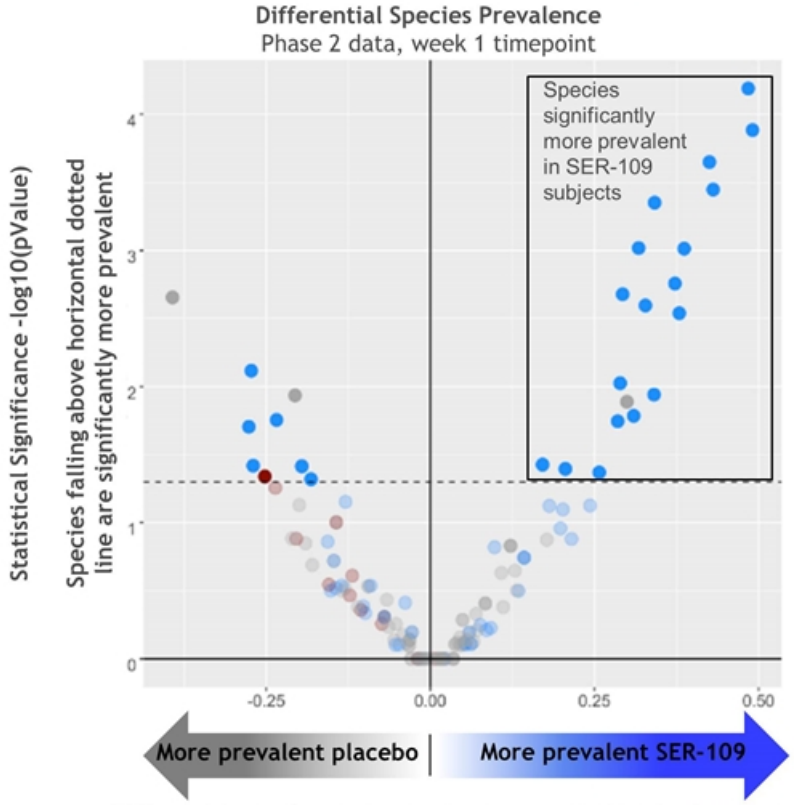
Increased prevalence of SER-109 associated bacterial species observed in Phase 2 patients treated with SER-109



Differential prevalence plot; non-transparent, colored points represent species that are significantly more prevalent in SER-109 or Placebo. Spore-former species (blue), opportunistic pathogens (maroon), other (grey)

- 20 spore-forming species were significantly more prevalent in subjects treated with SER-109 as compared to placebo
  (Note: some points are overlapping and appear as a single point in plot)
- 6 spore-forming species were significantly more prevalent in placebo treated subjects
- Opportunistic pathogens were more prevalent in placebo treated subjects
  (Note: none were more prevalent in SER-109 subjects)

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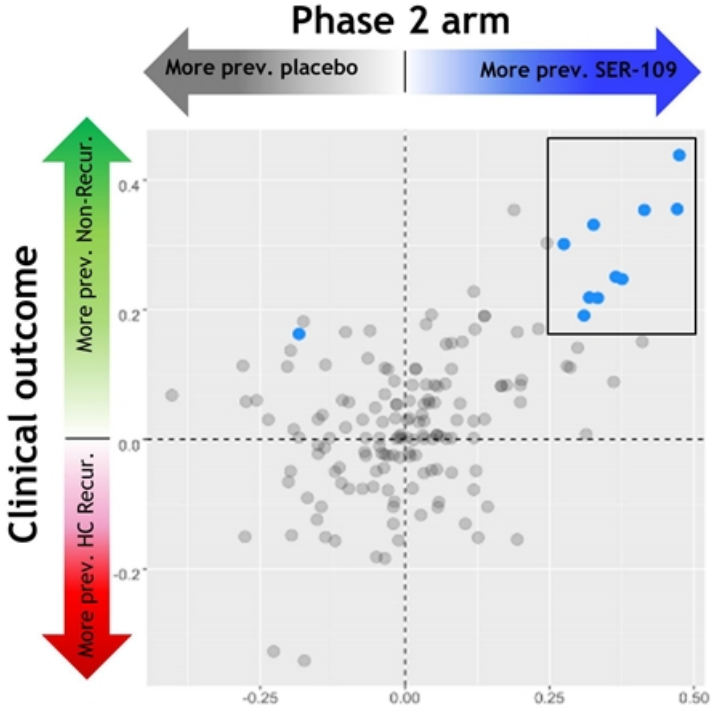
Microbiome signatures specific to SER-109 treatment may lead to positive clinical outcome



Differential prevalence plot; 1-week data; colored points represent species that are significantly more prevalent in arm:outcome category

HC-R indicates high confidence recurrences, defined as recurrences associated with a positive *C. diff.* cytotoxin diagnostic test

- Commensal spore-former species richness is significantly less in cytotoxin-positive recurrent subjects versus non-recurrent subjects (not shown)
- High-resolution genomic analyses have identified bacterial species that are significantly more prevalent in SER-109 treated subjects who did not recur (black box)
- Metabolomic functional analysis (not shown) provided supporting evidence of microbiome driven changes in metabolic activity that may increase pathogen resistance

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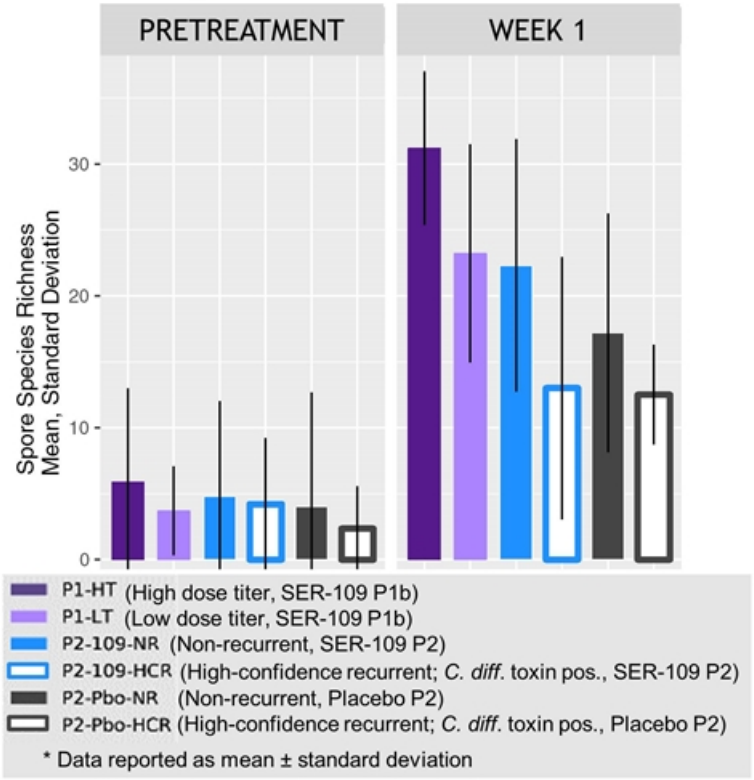
Dose impacts Phase 1b vs. Phase 2 microbiome dynamics



- Phase 1b subjects who received a higher dose (dark purple) achieved a significantly greater increase in diversity of commensal spore-former bacteria by 1wk post-treatment as compared to all other groups
- Phase 1b (light purple) and Phase 2 (blue) subjects treated with a comparable dose had similar increase in spore-former richness
- Above differences were maintained at 8 weeks post-treatment (not shown)
- Placebo treated subjects (grey) had weaker response than SER-109 treated subjects (blue)
- Both SER-109 and placebo treated cytotoxin-positive recurrent subjects (outlined bars) had reduced diversity of spore-forming species

Analyses suggest that suboptimal dosing in some patients may have contributed to the previously reported SER-109 Phase 2 study outcome

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SER-109 Phase 2 CMC Analyses

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CMC: Detailed analyses did not reveal any detectable causative issues

- Several steps in the manufacturing and formulation SER-109 process were different between the Phase 1b and the Phase 2 studies
  - Changes in manufacturing to increase the purity of the SER-109 spores
  - Changes in formulation (capsule design) to enable higher throughput manufacturing
- Detailed analyses have not revealed any statistically significant differences between the Phase 1b and Phase 2 materials including:
  - Spore viability and dose, as measured by culture assays and mouse *C. difficile* preclinical challenge model
  - Spore diversity, as measured by genomic assay
  - Excipient profile

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Next Steps for SER-109 development

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Strong rationale for further SER-109 clinical development

- Phase 2 analysis data suggest parameters for future clinical development of SER-109
  - **Diagnosis -** Utilization of *C. difficile* cytotoxin assay for both patient study inclusion and assessment of recurrence endpoint
  - **Dose** - Increased SER-109 dosage seeking to favor a rapid increase in microbiome diversity following antibiotic treatment
    - Favorable safety profile observed to date supports increasing dose
- High unmet medical need remains for an effective, safe, oral therapy for recurrent *C. difficile* infection
- FDA discussions regarding a new clinical study of SER-109 are in progress

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