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): June 12, 2017

SERES THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-37465 (Commission File Number) 27-4326290 (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)

Derecommencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 $extsf{ extsf{ iny line integral}}$

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 June 12, 2017, Seres Therapeutics, Inc. (the "Company," "we," and "our") posted an updated corporate slide presentation, including reaffirmed financial guidance and information regarding the Company's clinical trials, on its website at <u>www.serestherapeutics.com</u>. Updated clinical trial disclosures include (i) the initiation of the SER-109 ECORSPOR III study; (ii) the designation of the SER-109 ECOSPOR III study as a Phase 3 trial; and (iii) the planned expansion of the SER-262 Phase 1b study and the resulting modification in the timing of expected study results to early 2018. 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.

Seres Therapeutics, Inc. Corporate Slide Presentation as of June 12, 2017

(d) Exhibits.

Exhibit No.

99.1

Exhibit Description

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this report that do not relate to matters of historical fact should be considered forward-looking statements, including the planned expansion for the SER-262 Phase 1b study and the timing of study results for the SER-262 Phase 1b study.

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 are currently 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 May 7, 2017 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 report. Any such forward-looking statements represent management's estimates as of the date of this 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 forwardlooking statements should not be relied upon as representing our views as of any date subsequent to the date of this 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.

Date: June 12, 2017

SERES THERAPEUTICS, INC.

By: <u>/s/ Thomas J. DesRosier</u>

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

EXHIBIT INDEX

Exhibit No. 99.1

Seres Therapeutics, Inc. Corporate Slide Presentation as of June 12, 2017

Exhibit Description



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. 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 Investor highlights





The microbiome is essential to human health

Infectious Disease

- A diverse microbiome resists colonization by exogenous pathogens
- Exposure to broad spectrum antibiotics, and resulting gut microbiome dysbiosis, increase risk for *C. difficile* infection and colonization / infection by multi-drug resistant organisms

Inflammation and Immunology

- Microbiome known to alter regulatory T cells and Th17 T cell activation
- Role in inflammatory bowel disease (Ulcerative colitis and Crohn's disease) as well as allergy, rheumatoid arthritis and multiple sclerosis
- The composition of the microbiome has been demonstrated to impact the efficacy and safety of immuno-oncology checkpoint inhibitors

Metabolic Disease

- Effects on liver function, glucose utilization, and caloric availability
- Microbiome, and bacterial bile acid metabolism, implicated in several metabolic diseases (e.g. diabetes, obesity, liver diseases)

Selected references: Infectious disease / C. difficile: Leffler and Lamont, NEJM, 2015; Ulcerative colitis: Paramsothy et al. Lancet, 2017; Moayyedi et al. Gastroenterology, 2015; Immuno-oncology: Vetizou M et al., Science 2015.; Slvan A. et al., Science 2015.; Dubin et al., Nature, 2016. NASH: Le Roy et al., Hepatology, 2012. Metabolic syndrome: Perry et al. Nature, 2016, Ridaura VK et al., Science 2013. Primary sclerosing cholangitis Tabibian JH et al., Hepatology, 2016





Business strategy

Focused clinical efforts

 Prioritize serious diseases where dysbiosis of the gut microbiome has a causal role

C. difficile infection

Inflammatory bowel disease

World class, differentiated, microbiome expertise

- Computational biology
- Basic microbiome research
- Microbiology
- Translational science
- Clinical development
- Advanced manufacturing

Research in new therapeutic areas

 Collaborate with leading academic centers to advance research in promising therapeutic areas





Robust microbiome therapeutics pipeline

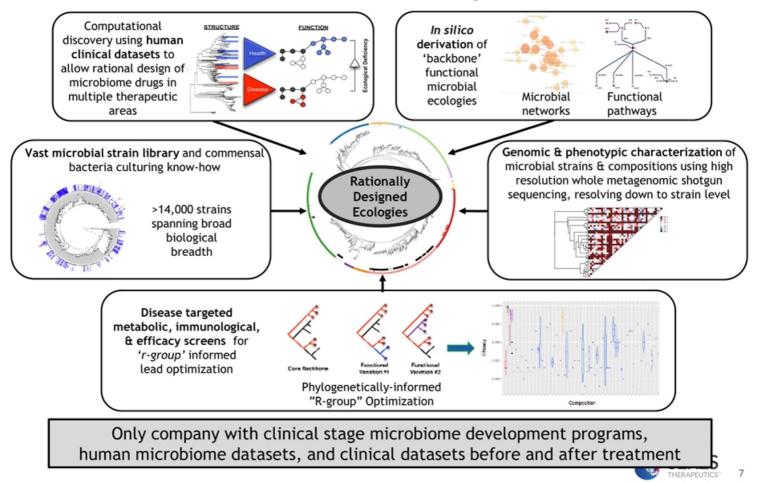
			PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
+	SER-109	Recurrent C. difficile				
¢	SER-262	Primary C. difficile				
+	SER-287	Ulcerative colitis				
¢	SER-301	Inflammatory Bowel Disease (IBD)				
¢	SER-155	Prevention of infection and GVHD following hematopoietic stem cell or solid organ transplant				
🗘 S	ynthetically fei	mented 🛛 🕂 Biologically sourced 🛛 📄 In	fectious 📄	Inflammatory		
DISC	OVERY EFFORT	S	ACADEMIC	COLLABORATOR		
Imm	uno-oncology an	d hematopoietic stem cell transplant	Memorial Cancer Ce	Sloan Kettering nter		
Inflar	mmatory bowel	diseases	A Per	in 🕦	St. Joseph's	
Prima	ary sclerosing ch	olangitis, NASH and other liver diseases	FP ^{MA}	YO CLINIC		
Obesity/metabolic syndrome		MASS GENE	ACHUSETTS RAL HOSPITAL			
	Genetic metabolic diseases					

Based on interactions with the U.S. Food and Drug Administration, ECOSPOR III will be designated a Phase 3 trial and the company expects that this single pivotal study may support SER-109 registration and approval.

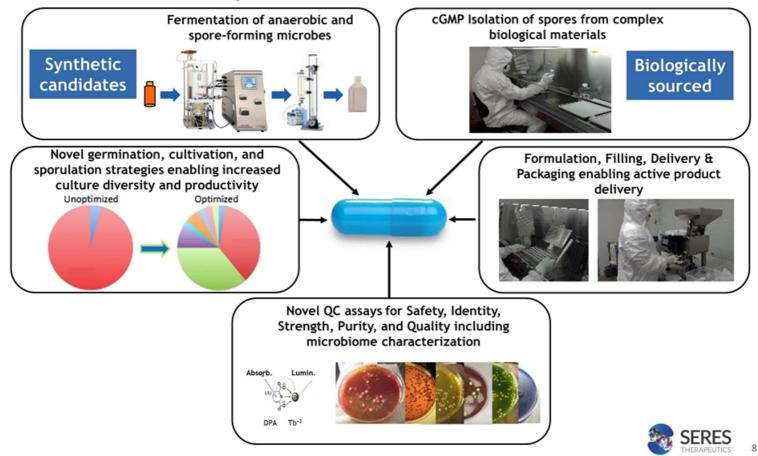
Collaboration with Nestlé Health Science regarding C. difficile and IBD programs for markets only outside of North America



Differentiated microbiome R&D platform



CMC platform enables manufacture of cGMP-compliant, oral, microbiome therapeutic candidates



Clostridium difficile Infection Overview and R&D Programs



Leading the Microbiome Revolution

C. difficile infection overview

- Infectious disease caused by toxin producing anaerobic, spore-forming bacteria, resulting in diarrhea, abdominal pain, fever, and nausea
- <u>Leading cause of hospital-acquired</u> <u>infection in the US;</u> approximately 29,000 deaths/year
- Infection caused by two-hit process: Disruption of gut microbiome and exposure to pathogenic spores
- ~25% of patients with primary CDI recur
- Risk of relapse increases with each recurrence





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Leffler and Lamont, New England Journal of Medicine, 2015

Treatment landscape & disease burden

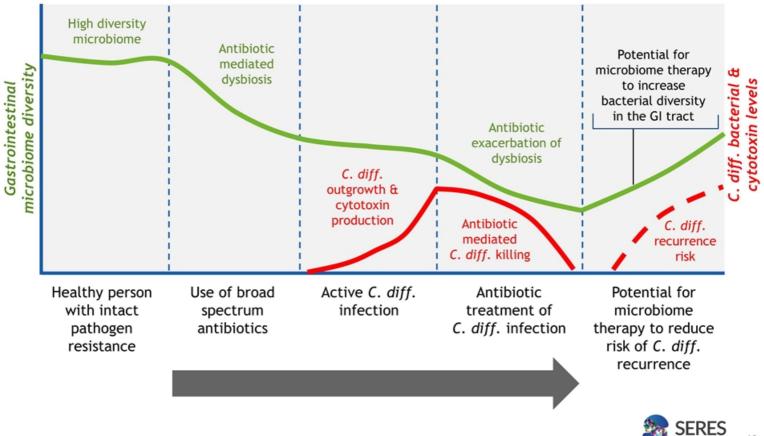
Modality	Characteristics		
Antibiotics	 Perpetuates microbiome dysbiosis, creating <i>C. difficile</i> infection susceptibility High recurrence rates, especially in recurrent cases 		
Fecal Transplant	 Invasive procedures (colonoscopy or NG-tube) Potential for transmission of human pathogens No FDA approved products 	High Unmet	
Antibodies	 Limited efficacy in Phase 3 studies Does not address underlying microbiome dysbiosis Complex administration, not patient-friendly 	Medical Need	
Vaccines	 Unproven efficacy until Phase 3 is complete Complex to identify and vaccinate elderly at-risk groups 		
 Economic burden as high as \$4.8B in U.S. acute-care facilities¹ Recurrent CDI episode ~\$18K²; >\$50K for cycle of recurrences 			

SERES 🗞

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1. Dubberke and Olsen, Clinical Infectious Diseases 2012; 2. Ghantoji et al., Journal of Hospital Infection, 2010.





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 <i>C. diff.</i> at 8 weeks 	 SER-109: 44% (26 of 59) recurrence Placebo: 53% (16 of 30) recurrence Relative risk recurrence between arms not significant
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%)

Phase 1b study results: Khanna et al. The Journal of Infectious Diseases; Phase 2 results: see July 31, 2016 press release (study results), and January 31, 2017 press release (Phase 2 study analyses)



SER-109 Phase 2 study post read-out analyses and findings

SER-109 analyses	Key issues addressed	
Clinical	 Detailed analyses of clinical data Investigation of <i>C. difficile</i> 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 	

Key Findings: Factors contributing to SER-109 Phase 2 study result

Diagnosis - Misdiagnoses may have occurred both in some patients entering the trial, as well as for recurrences diagnosed during the study

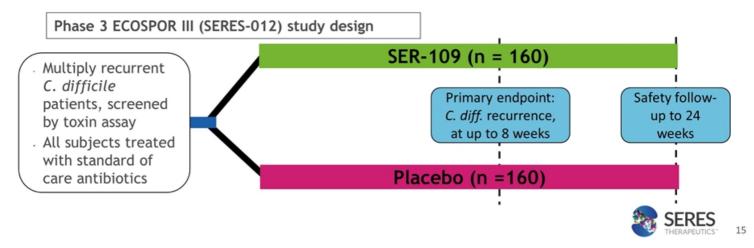
Dose - The dose used in the Phase 2 study may have been suboptimal in certain patients

See January 31, 2017 press release for additional information



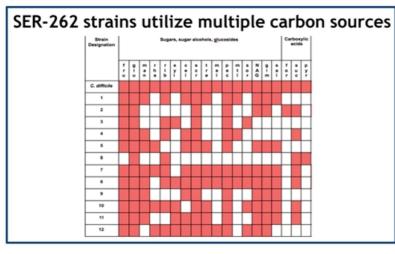
Phase 3 SER-109 ECOSPOR III study now underway

- Seres and FDA agreement on key design elements of a SER-109 Phase 3
- Based on FDA feedback ECOSPOR III designated as a Phase 3 study
- The ECOSPOR III Phase 3 study is the first pivotal trial in the emerging field of oral microbiome therapeutics
- ECOSPOR III to utilize a SER-109 dose approximately 10-fold higher than the dose used in the prior Phase 2 study, administered over three days



SER-262: Synthetic Ecobiotic[®] therapeutic candidate for primary *C. difficile* infection

- Oral, microbiome therapeutic candidate comprising twelve strains of fermented, rationally selected bacterial spores
- Bacteria species selected based on analysis of SER-109 Phase 1b microbiome data, biological and phylogenetic heterogeneity, and preclinical efficacy in *C. difficile* infection mouse model
- Data support a mechanism of action in which SER-262 strains compete for *C. difficile* preferred carbon sources

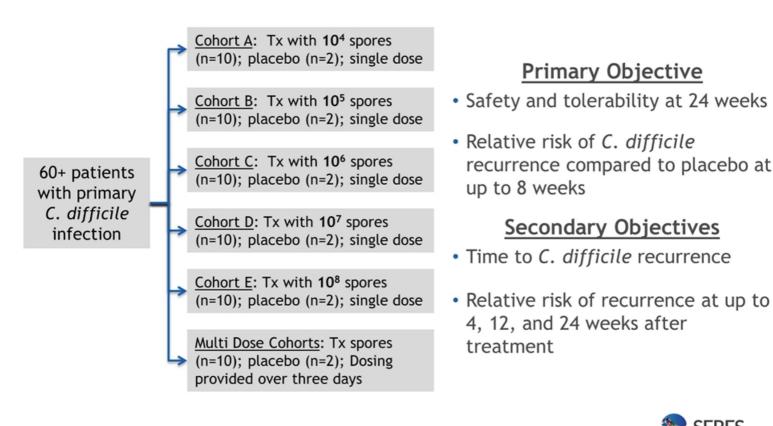




For additional information, see 2016 American Society of Microbiology conference poster, available on Seres website under 'Our Science'



SER-262 Phase 1b dosing study in patients with primary C. *difficile* infection



Inflammatory Bowel Disease Overview and R&D Programs



Leading the Microbiome Revolution

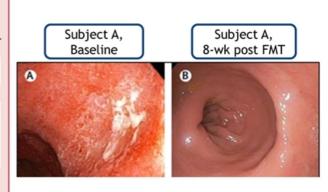
Multiple FMT studies provide proof of concept for microbiome therapy in ulcerative colitis

THE LANCET

Multidonor intensive faecal microbiota transplantation for active ulcerative colitis: a randomised placebo-controlled trial

Sudarshan Paramsothy, Michael A Kamm, Nadeem O Kaakoush, Alissa J Walsh, Johan van den Bogaerde, Douglas Samuel, Rupert W L Leong, Susan Connor, Watson Ng, Ramesh Paramsothy, Wei Xuan, Enmoore Lin, Hazel M Mitchell, Thomas J Borody

		Risk ratio (95% CI)	p value
11 (27%)	3 (8%)	3.6 (1.1-11.9)	0-021
18 (44%)	8 (20%)	2-2 (1-1-4-5)	0-021
22 (54%)	9 (23%)	2-4 (1-3-4-5)	0-004
5 (12%)	3 (8%)	1.6 (0.4-6.4)	0.48
13 (32%)	4 (10%)	3-2 (1-1-8-9)	0-016
	transplantatio (n=41) 11 (27%) 18 (44%) 22 (54%) 5 (12%)	transplantation (n=41) (n=40) 11 (27%) 3 (8%) 18 (44%) 8 (20%) 22 (54%) 9 (23%) 5 (12%) 3 (8%)	transplantation (n=41) (n=40) (95% Cl) 11 (27%) 3 (8%) 3-6 (1-1-11-9) 18 (44%) 8 (20%) 2-2 (1-1-4-5) 22 (54%) 9 (23%) 2-4 (1-3-4-5) 5 (12%) 3 (8%) 1-6 (0-4-6-4)



*Total Mayo score ≤2, with all subscores ≤1, and ≥1 point reduction from baseline in endoscopy subscore. †Combined Mayo subscores of ≤1 for rectal bleeding plus stool frequency. ‡Decrease of ≥3 points or ≥50% reduction from baseline (or both) in combined Mayo subscores for rectal bleeding plus stool frequency. \$Mayo endoscopy subscore 0. ¶Mayo endoscopy subscore ≤1, with ≥1 point reduction from baseline.

Table 2: Primary and secondary outcomes at week 8



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Selected references: Paramsothy et al. Lancet, 2017; Moayyedi et al. Gastroenterology, 2015

SER-287 Inflammatory Bowel Disease (IBD) opportunity

Significant unmet need for improved therapies for IBD

- Large US population: ~700K ulcerative colitis, ~700K Crohn's
- Over half of patients do not respond to biologic therapies
- Many therapies are immunosuppressive, limiting widespread use

SER-287 target profile:

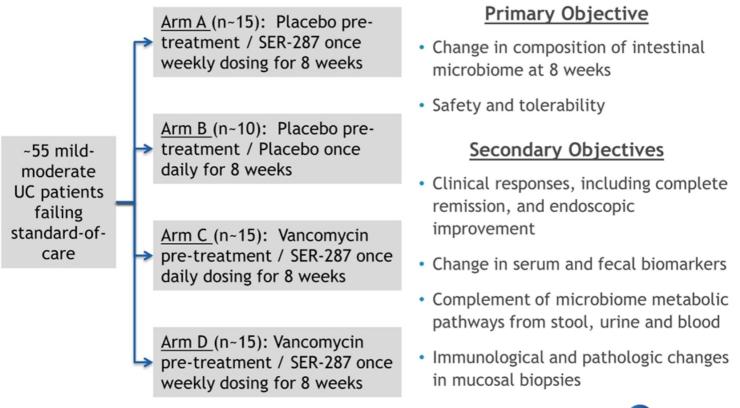
- Oral
- Alternative mechanistic approach, potential mono or combo therapy
- Not expected to be immunosuppressive

SER-287 development opportunity:

- · Initial development as induction therapy for ulcerative colitis
- Potential development as UC maintenance therapy, Crohn's disease



SER-287 Phase 1b study in ulcerative colitis patients is fully enrolled





SER-301: Synthetic Ecobiotic[®] therapeutic candidate for inflammatory bowel disease

- Follow-on therapeutic candidate to SER-287 in preclinical development for inflammatory bowel disease
- Oral, microbiome therapeutic candidate comprising fermented, rationally selected bacteria
- Selection of SER-301 bacterial composition to be based on:
 - SER-287 study data (clinical and microbiome analysis)
 - $_{\odot}$ Existing collaborations evaluating analysis of FMT ulcerative colitis clinical study data
 - Preclinical screening for microbial function, immunological assay, and animal models



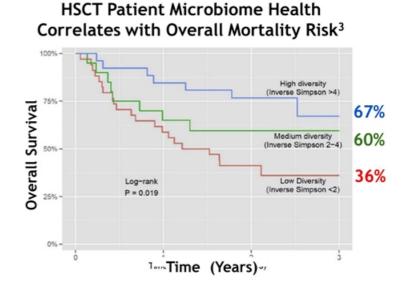
Additional R&D Opportunities



Leading the Microbiome Revolution

SER-155: Synthetic Ecobiotic[®] therapeutic candidate to improve transplantation outcomes

- Ecobiotic® synthetically derived therapeutic candidate to improve outcomes in patients receiving allogeneic hematopoietic stem cell transplantation (HSCT) or solid organ transplants
- Designed to reduce both infection risk, and Graft vs. Host Disease (GvHD)



¹ Khanna *et a*l, Journal of Infectious Disease 2016 ² Jenq, *et al*, Biology of Blood and Marrow Transplantation 2015, ³ Taur, *et al.*, Blood 2015.

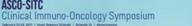


Immuno-oncology microbiome therapeutic opportunity

Therapeutic Objectives

- To improve efficacy: Modulate immune response, improve clinical response to therapeutic checkpoint inhibitors
- <u>To improve safety</u>: Reduce anti-CTLA4 induced colitis by providing microbial ecologies correlated with improved patient outcomes

ASCO-SITC



Association of diversity and composition of the gut microbiome with differential responses to PD-1 based therapy in patients with metastatic melanoma.

Jerry

Freek

J Clin Oncol 35, 2017 (suppl 7S; abstract 2)

Author(s):

Citati

Autoropy. Vancheswaran Gopalakrishnan, Christine Spencer, Alexandre Reuben, Tattana Karpinets, Diane Hutchinson, Kristi Hoffman, Peter A. Prieto, Michael T. Tetztaf, Alexander Lazaz, Michael A. Davies, Jeffrey E. Gershenwald, Robert R. Jeno, Patrick Hwu, Padmanee Sharma, James Patrick Allison, Andrew Futheal, Nadimul, Alexeph Petrosino, Carrier Daniel-MacDougall, Jennier R. Vilargo, UT MD Anderson Cancer Center, Houston, TX: The University of Texas MD Anderson Cancer Center, Houston, TX: Baylor College of Medicine, Houston, TX; Memor Sloan-Kettering Cancer Ctr, New York, NY



Intestinal microbiome analyses identify melanoma patients at risk for checkpoint-blockade-induced colitis

Krica Duble^{12,3}, Margaret K. Caliahan^{4,5}, Koyu Ken⁶, Koya Khanin⁷, Agres Valle⁹, Lilan Ling⁹, Daniel No², Asie Gobourne⁹, Eric Littmenn⁹, Curits Hottenhowe^{4,6}, Eric G. Pamer^{12,10,4} & Jedd D. Welchok^{4,13,10,11}

Science.

Anticancer immunotherapy by CTLA-4 blockade relies on the gut microbiota

Marie Vétizou^{1,2,3}, Jonathan M. Pitt^{1,2,3}, Romain Daillère^{1,2,3}, Patricia Lepage⁴, Nadine Waldschmit... + See all authors and affiliations

Science 27 Nov 2015: Vol. 350, Issue 6264, pp. 1079-1084 DOI: 10.1126/science.aad1329

Science.

Commensal Bifidobacterium promotes antitumor immunity and facilitates anti-PD-L1 efficacy

Ayelet Sivan^{1,*}, Leticia Corrales^{1,*}, Nathaniel Hubert², Jason B. Williams¹, Keston Aquino-Michaels³, Zachary... + See all authors and affiliations

Science 27 Nov 2015: Vol. 350, Issue 6264, pp. 1084-1089



Collaborations with leading institutes to advance R&D progress

Target Indication	Academic Collaboration		
Inflammatory Bowel Disease	St. Joseph's Healthcare & Hamilton		
Immuno-oncology Therapeutics	Memorial Sloan Kettering Cancer Center		
Hematopoietic Stem Cell Transplantation	Memorial Sloan Kettering Cancer Center		
Primary Sclerosing Cholangitis, NASH and Other Liver Diseases	CLINIC CLINIC		
Obesity and Metabolic Syndrome	MASSACHUSETTS GENERAL HOSPITAL		
Rare genetic metabolic diseases (e.g., urea cycle disorders, hepatic encephalopathy)	Research Pressient		

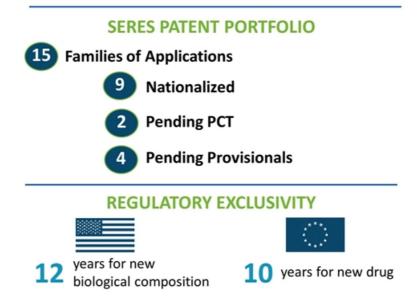
Collaboration announcements: Mayo Clinic, see June 6, 2016 press release; Memorial Sloan Kettering, University of Pennsylvania, see May 12, 2016 press release; Medical University of Graz and Research Institute of St. Joseph's Hamilton, see May 4, 2016 press release; Massachusetts General Hospital, see June 22, 2016 press release.



Broad IP portfolio and regulatory exclusivity

7 ISSUED US PATENTS + LICENSED IP*

- · Demonstrates rationally designed ecologies of spores and microbes are patentable
- · Composition of matter and method claims
- Claims related to SER-109/CDI & colitis lead candidates through 2033



* Includes additional rights to intellectual property including a worldwide exclusive license to Memorial Sloan Kettering Cancer Center patent applications related to the use of bacterial compositions for treating HSCT patients and related areas



Strong financial position

Resources to operate through 2018

Balance Sheet	As of Mar. 31, 2017	
Cash, cash equivalents and investments	\$202 M	

Income Statement	Latest Quarter, as of Mar. 31, 2017		
R&D	(\$20 M)		
G&A	(\$9 M)		
Net loss	(\$25 M)		

Common shares outstanding

40.4 M, as of Mar. 31, 2017

SER-109 Phase 3 study initiation triggers a \$20 million milestone payment from Nestlé Health Science



Upcoming value-driving milestones

SER-287: Ulcerative Colitis - Phase 1b read-out (H2 2017)

SER-262: Primary C. difficile infection - Phase 1b read-out (by early 2018)

Advancing new pipeline programs in infectious diseases, inflammatory and immune diseases (including immuno-oncology), metabolic and liver diseases

