

## Jefferies Healthcare Conference

June 7, 2023

#### **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 timing of VOWST product availability; the anticipated supply and degree of market acceptance of VOWST; 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; the receipt of milestone payments and access to additional debt tranches; 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 May 9, 2023, 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.



# VOWST<sup>™</sup> - First FDA Approved Orally Administered Microbiota-Based Therapeutic



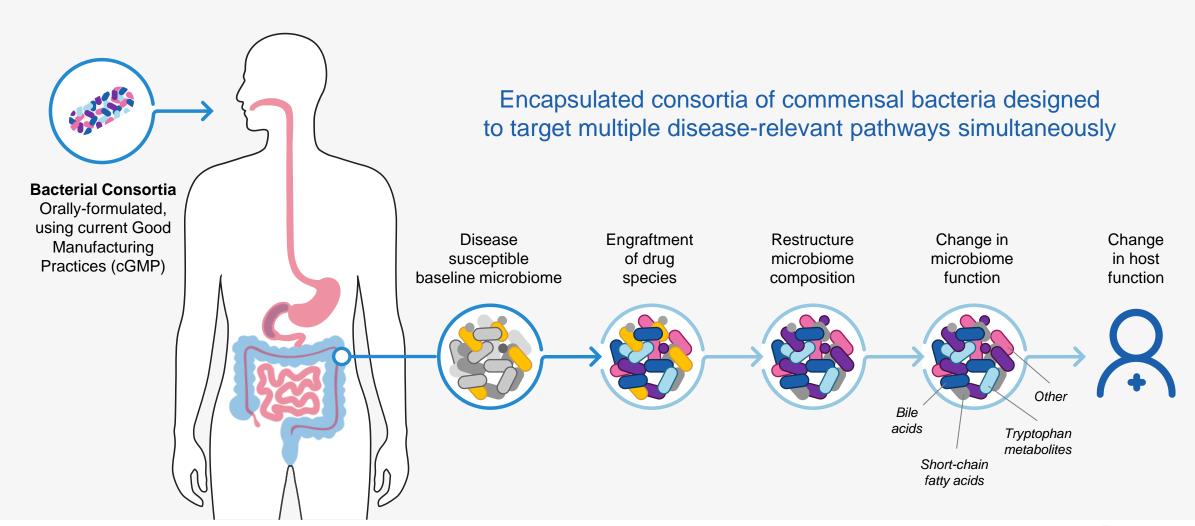
VOWST<sup>™</sup> is indicated to prevent the recurrence of *C. difficile* infection (CDI) in individuals 18 years of age or older following antibacterial treatment for recurrent CDI (rCDI).



Seres is pioneering a new modality, led by VOWST™



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





#### Strategic Priorities | Expanding Microbiome Therapeutic Leadership

**Successfully commercialize** VOWST™, first-in-class oral microbiome therapeutic

FDA approved on April 26, 2023

\* allo-HSCT: allogeneic hematopoietic stem cell transplant; GvHD: graft versus host disease

and Drug Administration (FDA)

- Commercially available
- Co-commercialization agreement with Nestlé Health Science

Maximize opportunities in **Infection Protection** 

- SER-155 Phase 1b study in allo-HSCT\* patients for prevention of bacterial infections and acute GvHD\*
- SER-155 Phase 1b Cohort 1 Day 100 data support continued development
- Preclinical portfolio to prevent infection in medically compromised patients, including cancer neutropenia, cirrhosis and solid organ transplant

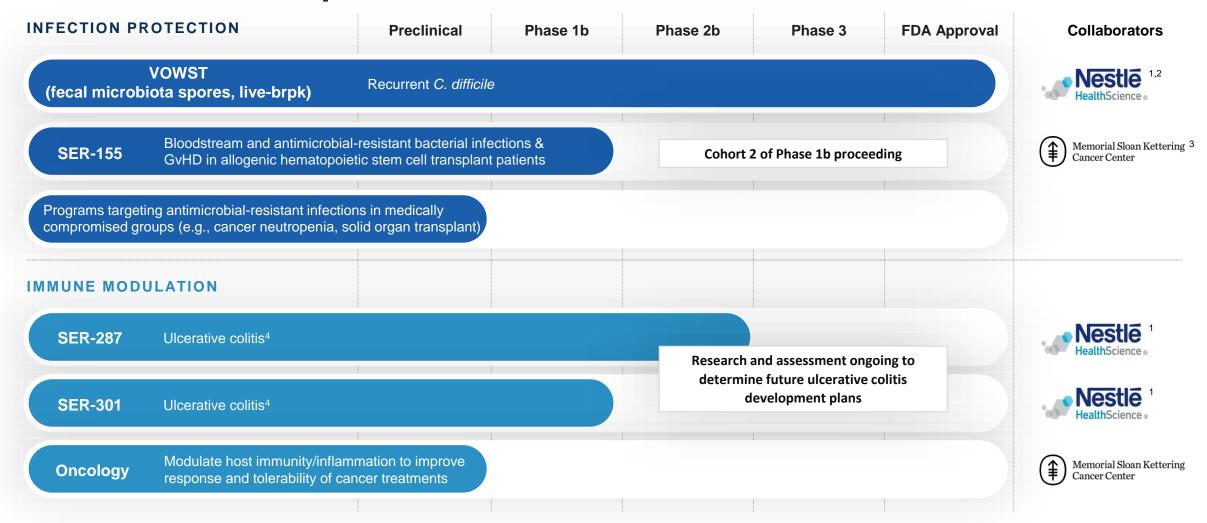
Continue research to inform further development in ulcerative colitis and immune modulation

- Assessment of potential to utilize biomarker-based patient selection in Ulcerative Colitis underway
- SER-155 GvHD results may further inform path forward in immune modulation.

SER-155 is an investigational microbiome therapeutic that has not been approved by any regulatory authority, including the U.S. Food



# VOWST is the First Approval from Our Pipeline of Oral 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. VOWST 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



VOWST<sup>TM</sup> and Recurrent *C. difficile* Infection





#### C. difficile Infections Are an 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

**URGENT** 





40-50%

Risk of recurrence escalates once a patient has an initial recurrence, which can trap patients in a vicious cycle

<sup>2.</sup> 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.

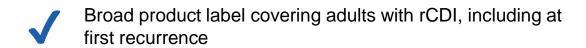


<sup>1.</sup> US CDC. Antibiotic Resistance Threats in the United States, 2019. US Department of Health and Human Services, CDC; 2019. doi:10.15620/cdc:82532

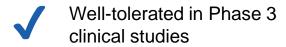
#### **VOWST Offers an Attractive Product Profile**

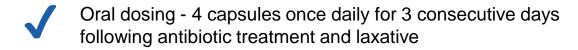
Highlights of Prescribing Information	
Indication statement	VOWST is indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI (rCDI)
Limitations of use	VOWST is not indicated for the treatment of CDI











No refrigeration requirements
Store in original packaging

#### Full prescribing information available at vowst.com



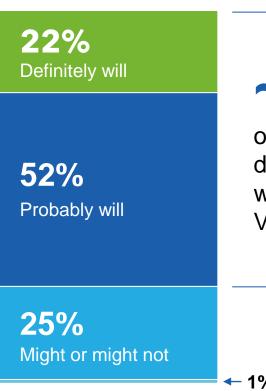
#### **VOWST** is Highly Anticipated by Healthcare Professionals

Recurrent *C. difficile* infection is a highly debilitating and life-threatening disease, and antibiotics alone do not address the underlying cause of rCDI, dysbiosis of the gut microbiome. The approval of VOWST provides an important new oral treatment option for this disease, and I am pleased to now be able offer this medicine to patients that have experienced a CDI recurrence.



Dr. Carl Crawford, M.D.
Assistant Professor of Clinical Medicine
Division of Gastroenterology, Weill Cornell
Medicine

#### **HCP Intent to Prescribe VOWST™**



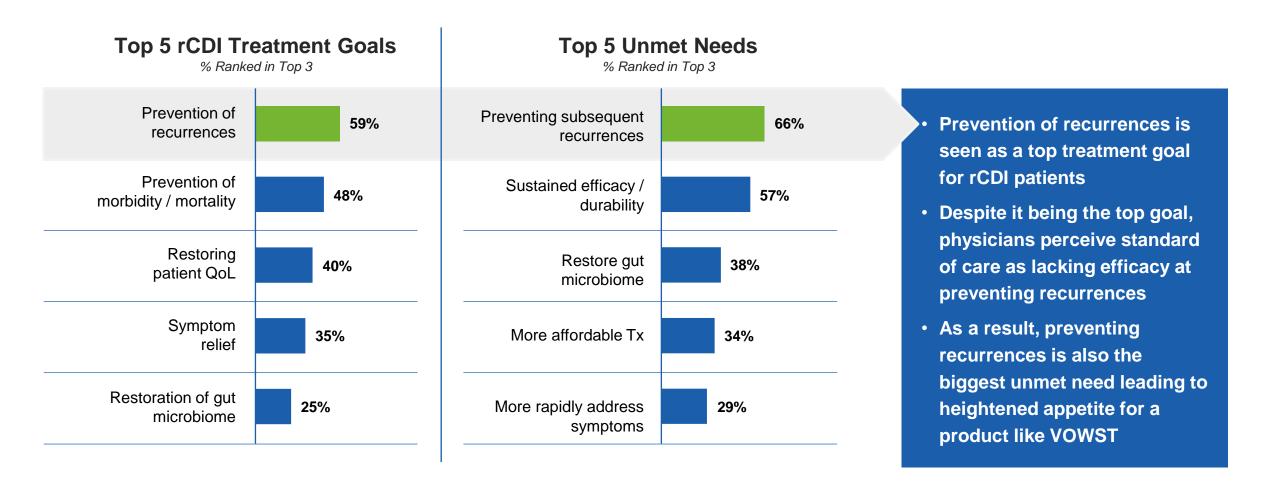
~75%

of surveyed HCPs definitely or probably will prescribe VOWST<sup>TM</sup>

◆ 1% Definitely or probably will not



# HCP Enthusiasm for VOWST Driven by Desire to Prevent Recurrences and Limitations of Current Options









Co-commercializing VOWST in the United States with 50/50 profit sharing per July 2021 agreement, extending global strategic collaboration



## **Combined Field Teams to Cover Highest Potential rCDI Prescribers**

Prioritize top volume and early adopting HCPs: 150-person GI sales force

- GI sales force covers 85% of GI practices for current inline Nestle product, ZENPEP
- Average 10 years industry experience & 5 years in GI
- Drove ZENPEP® acceleration over last 3 years

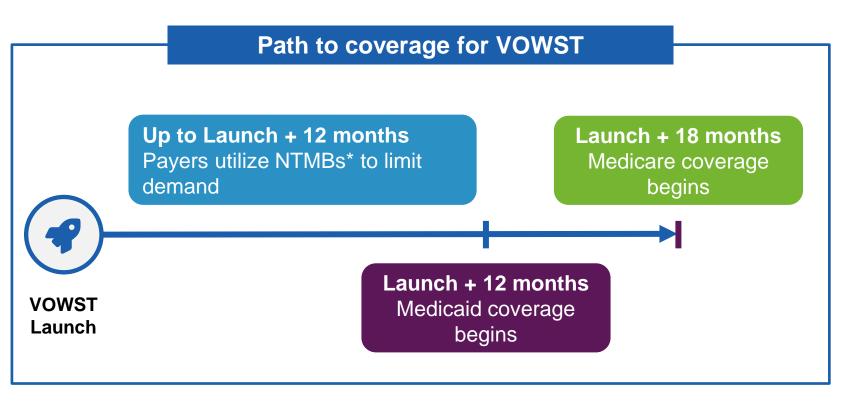
Prioritize ~300 top HCOs: **20-person hospital team** 

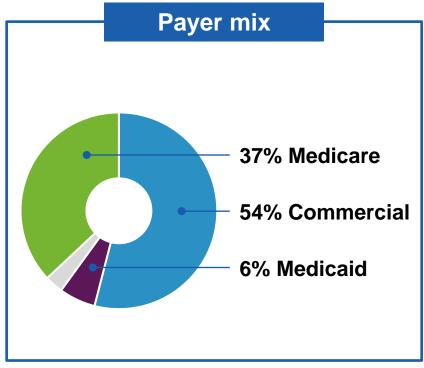
- Includes ID engagement; ~1500 ID specialists see > 2 rCDI patients/year
- Deployed Q1 '23; profiled top institutions

Activate broader HCP audience via non-personal and patient promotion



# **Engaging with Key Commercial and Medicare Part D Plans to Initiate Broad Coverage**







## VOWST Delivers Compelling Value Proposition We Are Committed to Broad Patient Access



Uniquely addresses **#1 unmet need** of preventing recurrence, with robust efficacy and an established safety profile with an orally administered regimen



Addresses **costly burden of rCDI**: \$43,000 cost / patient<sup>1</sup>



**Innovative product**; first and only FDAapproved orally administered microbiota-based therapeutic



Commitment to patient access and affordability



Providing financial and treatment support for eligible patients\*



## Laying the Foundations to Ultimately Transform Standard of Care

#### **Initial Focus**

- Increase HCP awareness and trial of an entirely new modality
- Provide positive experience
- Enhance hospital outflow
- Engage payers to build coverage

#### **Expanded Focus**

- Drive repeat use among highervolume HCPs
- Increase reach to lower-volume HCPs
- Optimize payer coverage with a focus on commercial plans



## Well Positioned to Supply Commercial Demand at Launch and Beyond

10+ years of Seres technology & facility investment for anaerobic bacterial therapeutics

Seres in-house GMP
Manufacturing and Quality Control

**High-quality CMO support** 









Bacthera collaboration provides redundancy and expands upon existing commercial supply capacity



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



Launch batches manufactured; anticipate Bacthera commercial drug production in 2024 for release in 2025, as the expected number of patients treated expands



**VOWST<sup>TM</sup>** 

commercial

supply

SER-155 and Infection Protection Franchise





## **Antimicrobial Resistant Infections - Urgent Public Health Threat**

#### **Major burden to society**



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



**\$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)

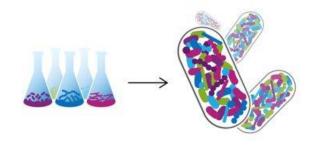
Limited innovation despite substantial and growing impact



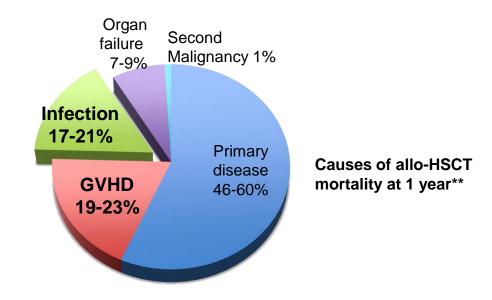
# SER-155 Designed to Modulate Targets that Address Leading Causes of Mortality Following Allogeneic HSCT (allo-HSCT)

SER-155 is an investigational 16-strain cultivated bacterial consortium optimized using MbTx platform

SER-155 specifically designed to reduce infections and GvHD in allo-HSCT recipients



- Consortium of unique, human commensal bacterial strains
- Cultivated and encapsulated for oral delivery
- Strain selection based on broad pre-clinical screening for defined functions and insights from microbiome clinical data
- Preclinical data show SER-155 leads to multi-log reductions of *Enterococcus* (including VRE) and *Enterobacteriaceae* (including CRE) linked to GvHD in allo-HSCT patients\*



Allo-HSCT recipients are medically vulnerable;
 50% 3 year mortality



<sup>\*</sup> Seres data shared in Jan 2022 Infection Protection Investor Event; VRE = vancomycin-resistant *Enterococci*; CRE = carbapenem-resistant *Enterobacterales*; VRE and CRE both included in US CDC Antibiotic Resistance Threats

\*\* CIBMTR 2020

# SER-155 May Represent a Novel Solution to Reduce GI Pathogen Abundance and Infection & GvHD in Allogeneic HSCT

- SER-155 is an oral, cultivated consortium, designed to reduce abundance of pathogens linked to infections and GvHD in allogeneic HSCT recipients\*
- SER-155 Phase 1b study Cohort 1
  - SER-155 well-tolerated through 100 Days post HSCT
  - SER-155 bacterial strain engraftment was as expected
  - GI pathogen domination was rare and transient in patients after SER-155 treatment compared to expected rates from prior cohort studies

Enrollment ongoing in SER-155 Phase 1b Cohort 2, a randomized, double-blind, placebocontrolled study

Expect topline results in mid-2024



## **ESKAPE** Pathogen Domination was Rare and Transient in Cohort 1

## ESKAPE pathogen domination\* in SER-155 administered subjects observed at rates substantially lower than reference cohort

#### SER-155 Cohort 1

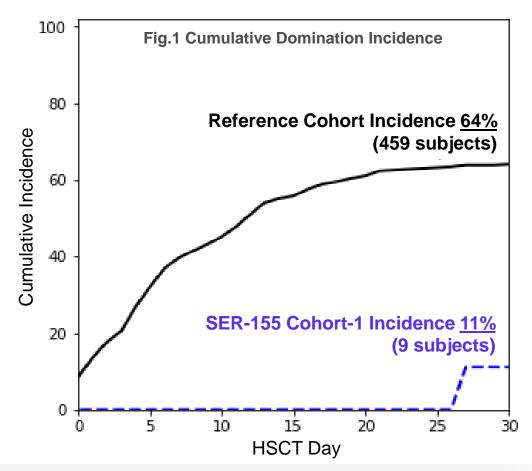
- From HSCT Day 0-30, 11% of patients (1 subject,
   Fig.1 blue line)
- From HSCT day 0-100, 22% of patients (2 subjects, not shown)
- All instances of pathogen domination were transient

## Reference Patient Cohort (MSKCC; Peled et al. 2020)

• Day 0 through 30, 64% of patients (Fig.1 black line)

Pathogen domination has been shown to be associated with risk of blood stream infections (Taur, CID 2012) and GvHD (Jenq Bio BMT 2015; Stein-Thoeringer Science 2019)

<sup>\*</sup> i.e., the families: Enterococcaceae, Enterobacteriaceae, Streptococcaceae & Staphylococcaceae





## **SER-155 Potential Integration into Allogeneic HSCT Treatment Regimen**

#### Unique potential clinical and economic value for allogeneic HSCT patients



# **Substantial impact for patients:** almost 30,000 transplants / year across US and Europe



**Favorable safety profile** appropriate for use across HSCT population



**Double benefit** of reducing infections and GvHD, 2 of 3 leading causes of mortality at 1 year



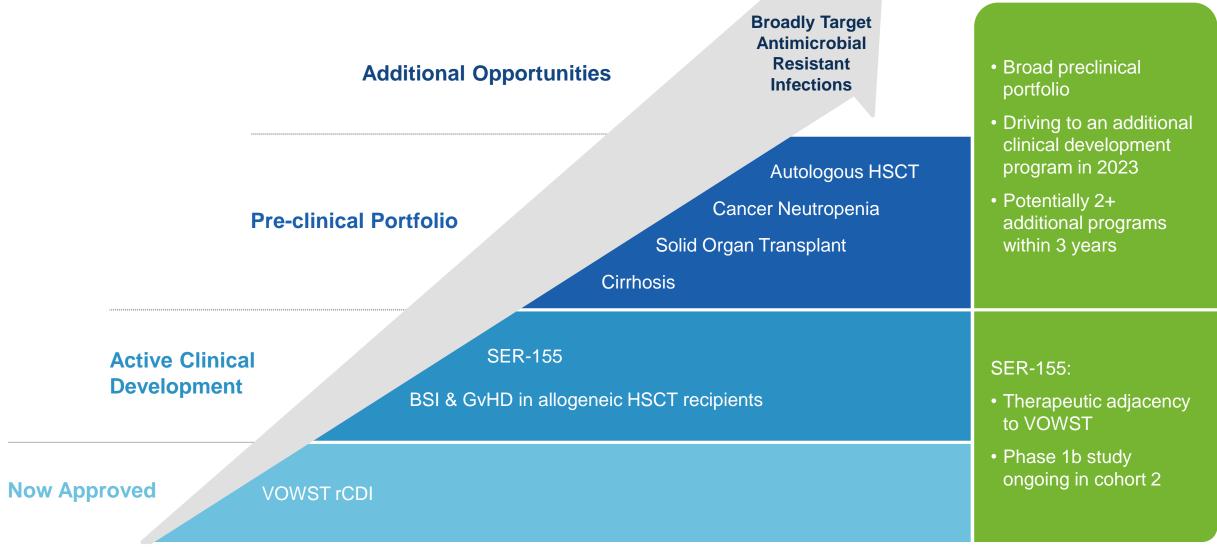
**Avoids costs** of post-transplant complications: \$181K average additional costs for US patients with complications



# Seres' Path **Forward**



#### **Maximizing the Opportunity in Infection Protection**





## Well Positioned to Bring VOWST to Patients and Advance Pipeline

3/31/2023 cash balance: \$106.5 million



\$125 million milestone received following VOWST approval



Secured up to \$250 million debt facility; \$110 million funded at closing<sup>1</sup>

Replaces existing debt facility

3/31/2023 pro-forma cash balance: \$282 million

including \$125 million VOWST<sup>™</sup> approval milestone and net proceeds\* received at closing from Oaktree

1. \$140 million of commitments may be borrowed if certain conditions are satisfied, including net sales targets of VOWST.



## Continued Microbiome Therapeutic Leadership, Anticipated Compelling Growth and Value Creation

2023

2025

VOWST<sup>™</sup> approved; commercialization underway in rCDI

Advancing opportunities in Infection Protection and other therapeutic areas



- VOWST<sup>™</sup> 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

