UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2026

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-37465

Seres Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-4326290**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
101 Cambridgepark Drive Cambridge, MA	**02140**
(Address of principal executive offices)	**(Zip Code)**

(617) 945-9626

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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	MCRB	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 2, 2026, the registrant had 10,195,031 shares of common stock, $0.001 par value per share, outstanding.

Seres Therapeutics, Inc.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or the Quarterly Report, contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report, including without limitation statements regarding our future results of operations and financial position including our projected cash runway, our requirement for additional funding, our business strategy, including potential strategic partnership efforts, our prospective products, the design, timing and results of our clinical studies and data readouts, product approvals, communications with, feedback from, or submissions to the FDA, research and development costs, timing and likelihood of success, our ability to continue as a going concern, our ability to maintain compliance with any applicable Nasdaq listing requirements, executive and director transition matters, plans and objectives of management for future operations and future results of anticipated products, or the timing of any of the foregoing, are forward-looking statements. These statements 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.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this report and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties and assumptions described under the sections in this report titled "Summary Risk Factors," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

TRADEMARKS, SERVICE MARKS AND TRADENAMES

We have proprietary rights to trademarks used in this Quarterly Report, which are important to our business and many of which are registered under applicable intellectual property laws. Solely for convenience, the trademarks, service marks, logos and trade names referred to in this Quarterly Report are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights to these trademarks, service marks and trade names. This Quarterly Report contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this Quarterly Report are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. "Risk Factors" in this Quarterly Report. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.
- We will need additional funding in order to advance development of our product candidates (including to conduct the Phase 2 study of SER-155 in allo-HCT and/or a next study of SER-155 in irEC and to advance our earlier stage programs) and commercialize our product candidates, if approved. If we are unable to raise capital or secure a partnership or other business development transaction, we could be required to implement further cost-reduction measures, reduce or delay our product

development programs or potential future commercialization efforts, or pursue other alternatives, which could include seeking relief under the U.S. Bankruptcy Code or winding down our operations.

- We are a clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We are early in our development efforts of our product candidates and may not be successful in our efforts to use our reverse translational platform to build a pipeline of product candidates and develop additional marketable drugs.
- Our product candidates are based on live biotherapeutics, which is a novel approach to therapeutic intervention.
- Clinical drug development involves a risky, lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and any potential future commercialization of our product candidates.
- Delays or difficulties in the enrollment of patients in clinical trials could result in our receipt of necessary regulatory approvals being delayed or prevented.
- Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, or policy changes could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.
- Current and future legislation or regulation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may adversely affect the prices we may obtain.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or any collaborators will not be able to commercialize our product candidates or will not be able to do so as soon as anticipated, and our ability to generate revenue will be materially impaired. Additionally, failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.
- We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.
- Even if any of our product candidates receive marketing approval, such product candidates may fail to achieve the degree of market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community necessary for commercial success.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- We have in the past and may again in the future receive a notice of the failure to satisfy a continued listing rule from Nasdaq.

PART I – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

SERES THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands, except share and per share data)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 17,528	$ 45,766
Accounts receivable due from SPN - related party	12,500	360
Accounts receivable	183	157
Prepaid expenses and other current assets	4,212	3,093
Total current assets	34,423	49,376
Property and equipment, net	2,999	7,635
Operating lease assets	27,662	72,483
Restricted cash	773	8,668
Other non-current assets	31	31
Total assets	$ 65,888	$ 138,193
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,461	$ 1,682
Accrued expenses and other current liabilities	3,504	3,972
Accrued liabilities due to SPN - related party	3,278	3,278
Operating lease liabilities	12,650	10,390
Total current liabilities	20,893	19,322
Operating lease liabilities, net of current portion	23,122	72,576
Other long-term liabilities	514	2,077
Total liabilities	44,529	93,975
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.001 par value; 360,000,000 shares authorized at September 30, 2026 and December 31, 2025; 10,049,501 and 9,556,466 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	10	10
Additional paid-in capital	1,025,370	1,016,611
Accumulated deficit	(1,004,021)	(972,403)
Total stockholders' equity	21,359	44,218
Total liabilities and stockholders' equity	$ 65,888	$ 138,193

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SERES THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME
(unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Grant revenue	593	351	1,687	351
Total revenue	593	351	1,687	351
Operating expenses:				
Research and development expenses	5,592	12,616	27,928	37,376
General and administrative expenses	5,448	9,476	20,579	31,617
Impairment of long-lived assets	5,705	—	11,512	—
Manufacturing services	—	736	—	5,952
Total operating expenses	16,745	22,828	60,019	74,945
Loss from operations	(16,152)	(22,477)	(58,332)	(74,594)
Other income (expense):				
Gain on sale of VOWST Business	—	27,222	25,000	79,588
Interest income	146	618	652	1,782
Other income (expense) (1)	(280)	2,841	1,062	14,255
Total other income (expense), net	(134)	30,681	26,714	95,625
Net (loss) income and comprehensive (loss) income	$ (16,286)	$ 8,204	$ (31,618)	$ 21,031
Net (loss) income per share attributable to common stockholders - basic	$ (1.63)	$ 0.94	$ (3.24)	$ 2.41
Net (loss) income per share attributable to common stockholders - diluted	$ (1.63)	$ 0.94	$ (3.24)	$ 2.40
Weighted average common shares outstanding - basic	9,982,031	8,758,692	9,764,763	8,735,418
Weighted average common shares outstanding - diluted	9,982,031	8,771,519	9,764,763	8,744,797

[1] Includes $0, $0, $2,028, and $11,827 for the three and nine months ended September 30, 2026 and 2025 related to reimbursement received from SPN (related party) for transition services provided by the Company.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SERES THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited, in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value			
Balance at December 31, 2025	9,556,466	$ 10	$ 1,016,611	$ (972,403)	$ 44,218
Issuance of common stock upon vesting of RSUs, net of tax withholdings	6,426	—	—	—	—
Issuance of common stock under ESPP	3,638	—	28	—	28
Issuance of common stock from at the market equity offering, net of issuance costs of $10	25,796	—	400	—	400
Stock-based compensation expense	—	—	1,766	—	1,766
Net loss	—	—	—	(19,913)	(19,913)
Balance at March 31, 2026	9,592,326	$ 10	$ 1,018,805	$ (992,316)	$ 26,499
Issuance of common stock upon vesting of RSUs, net of tax withholdings	2,957	—	—	—	—
Issuance of common stock from at the market equity offering, net of issuance costs of $140	232,286	—	1,715		1,715
Stock-based compensation expense	—	—	1,739	—	1,739
Net income	—	—	—	4,581	4,581
Balance at June 30, 2026	9,827,569	$ 10	$ 1,022,259	$ (987,735)	$ 34,534
Issuance of common stock upon vesting of RSUs, net of tax withholdings	2,686	—	—	—	—
Issuance of common stock from at the market equity offering, net of issuance costs of $106	113,643	—	741	—	741
Issuance of common stock in connection with lease termination	103,520	—	500	—	500
Issuance of common stock under ESPP	2,083	—	11	—	11
Stock-based compensation expense	—	—	1,859	—	1,859
Net loss	—	—	—	(16,286)	(16,286)
Balance at September 30, 2026	10,049,501	$ 10	$ 1,025,370	$ (1,004,021)	$ 21,359

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value			
Balance at December 31, 2024	8,650,227	$ 9	$ 991,874	$ (978,099)	$ 13,784
Issuance of common stock upon vesting of RSUs, net of tax withholdings	12,966	—	—	—	—
Issuance of common stock under ESPP	14,188	—	184	—	184
Issuance of common stock from at the market equity offering, net of issuance costs of $26	54,806	—	996	—	996
Stock-based compensation expense	—	—	2,819	—	2,819
Net income	—	—	—	32,682	32,682
Balance at March 31, 2025	8,732,187	$ 9	$ 995,873	$ (945,417)	$ 50,465
Issuance of common stock upon vesting of RSUs, net of tax withholdings	22,195	—	—	—	—
Stock-based compensation expense	—	—	2,340	—	2,340
Adjustment for fractional shares due to reverse stock split	100	—	—	—	—
Net loss	—	—	—	(19,855)	(19,855)
Balance at June 30, 2025	8,754,482	$ 9	$ 998,213	$ (965,272)	$ 32,950
Issuance of common stock upon exercise of stock options	782	—	15	—	15
Issuance of common stock upon vesting of RSUs, net of tax withholdings	5,749	—	—	—	—
Issuance of common stock under ESPP	3,651	—	46	—	46
Stock-based compensation expense	—	—	2,482	—	2,482
Net income	—	—	—	8,204	8,204
Balance at September 30, 2025	8,764,664	$ 9	$ 1,000,756	$ (957,068)	$ 43,697

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

SERES THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited, in thousands)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities:		
Net (loss) income	$ (31,618)	$ 21,031
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Stock-based compensation expense	5,364	7,641
Depreciation and amortization expense	1,932	3,179
Impairment of long-lived assets	11,512	—
Non-cash operating lease cost	5,171	6,234
Gain on sale of VOWST business	(25,000)	—
Loss on disposal of fixed assets	354	—
Changes in operating assets and liabilities:		
Accounts receivable due from SPN - related party	360	1,642
Accounts receivable	(26)	(351)
Prepaid expenses and other current and other non-current assets	1,244	2,701
Accounts payable	(221)	(2,402)
Accrued liabilities due to SPN - related party	—	(13,300)
Operating lease liabilities	(16,272)	(6,387)
Accrued expenses and other current and long-term liabilities	(2,031)	(4,161)
Net cash (used in) provided by operating activities	(49,231)	15,827
Cash flows from investing activities:		
Purchases of property and equipment	—	(223)
Sales of property and equipment	66	—
Proceeds from VOWST milestone termination payment	12,500	—
Net cash provided by (used in) investing activities	12,566	(223)
Cash flows from financing activities:		
Proceeds from at the market equity offering, net of issuance costs	2,856	996
Proceeds from exercise of stock options	—	15
Issuance of common stock under ESPP	39	230
Net cash provided by financing activities	2,895	1,241
Net (decrease) increase in cash, cash equivalents, and restricted cash	(33,770)	16,845
Cash, cash equivalents and restricted cash at beginning of period	54,434	39,461
Cash, cash equivalents and restricted cash at end of period	$ 20,664	$ 56,306
Supplemental disclosure of non-cash investing and financing activities:		
Reduction in ROU asset and lease liability due to lease modification	$ 30,422	$ —
Equity issued in connection with lease termination	$ 500	$ —

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

1. Nature of the Business and Basis of Presentation

Seres Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Delaware in October 2010 under the name Newco LS21, Inc. In October 2011, the Company changed its name to Seres Health, Inc., and in May 2015, the Company changed its name to Seres Therapeutics, Inc. The Company is a clinical-stage company focused on improving patient outcomes in medically compromised populations, including oncology patients and those suffering from inflammatory and immune ("I&I") diseases through discovery and development of novel live biotherapeutics. The Company led the successful development and approval of VOWST (previously referred to as SER-109), the first FDA-approved orally administered microbiome therapeutic and a Breakthrough Therapy designated drug, which was sold to Nestlé Health Science (as defined below) in September 2024. The Company's live biotherapeutic product ("LBP") candidates, including SER-155, SER-603, SER-428, SER-147, and other potential candidates in earlier development, are consortia of bacteria designed to optimize specific, targeted pharmacological properties, and are formulated for oral delivery. The Company is designing LBP candidates to address unmet medical needs in oncology that can lead to interruption to patients' cancer treatment and/or mortality, and to treat I&I diseases, by modulating host function to protect and improve mucosal epithelial barrier integrity, induce immune homeostasis and tolerance, and prevent the colonization and overgrowth of pathogens in the gastrointestinal ("GI") tract.

The Company's initial focus in oncology is in two areas: (1) to prevent bacterial bloodstream infections ("BSIs"), including those that can harbor antimicrobial resistance ("AMR"), as well as other pathogen-associated negative clinical outcomes in patients undergoing allogeneic hematopoietic stem cell transplantation ("allo-HCT"), and (2) to prevent immune checkpoint-related enterocolitis ("irEC"), a frequent and often severe side effect of immune checkpoint inhibitor ("ICI") therapy.

SER-155, the Company's most advanced LBP candidate, is an investigational, oral, live biotherapeutic currently in development to address unmet medical needs in oncology that cause interruptions to cancer treatment and/or mortality. In the Company's placebo-controlled Phase 1b study of SER-155 in allo-HCT, SER-155 was associated with a 77% relative risk reduction in bacterial BSIs and a significant reduction in systemic antibiotic exposure as well as a lower incidence of febrile neutropenia, as compared to placebo through day 100 post HCT. SER-155 was generally well tolerated, with no observed treatment-related serious adverse events. Drug pharmacology data demonstrated that SER-155 significantly promoted mucosal epithelial barrier integrity and had a positive impact on biomarkers of systemic inflammation and immune homeostasis. Following advancement of key startup activities for the SER-155 Phase 2 study in allo-HCT, including the submission of a final protocol to the FDA in January 2026, study site evaluation and qualification with its CRO, and manufacturing of drug substance, the Company has paused additional investment in that program while continuing to seek funding for the Phase 2 study.

SER-155 is also being developed to prevent irEC, with the aim of enabling patients to continue their ICI cancer therapy and avoid the need for immunosuppressive steroid treatment. irEC is among the most frequent and severe immune-related adverse events ("irAEs"), in recipients of ICI therapy, and can be observed in up to 50% of ICI patients, with rates varying based on cancer drug and treatment regimen. Moderate to severe (Grade 2-3) irEC occurs in approximately 25% of all ICI therapy recipients in the United States. Clinical guidelines for patients who experience Grade 2 or higher irEC require treatment, which could include halting of ICI cancer treatment and initiating a systemic immunosuppressive corticosteroid, a biologic, or both, which are associated with clinically meaningful toxicities and other negative consequences, including systemic immunosuppression, increased infection risk, metabolic complications, and potential interference with cancer treatment. SER-155 was evaluated in 15 patients with moderate-to-severe irEC through an investigator-sponsored trial ("IST"), with Memorial Sloan Kettering Cancer Center, with whom the Company has had a decade-long collaboration. Top-line data from the IST showed that 80% of SER-155 recipients achieved an immunosuppressive-free clinical response of diarrhea (a primary symptom of irEC) at Day 15, which met the primary endpoint, defined as at least a 1-grade improvement in diarrhea symptoms without immunosuppressive therapy (i.e., a corticosteroid and/or biologic immunomodulator drug). All 12 participants with immunosuppressive-free clinical response at Day 15 had the same, or better, diarrhea grade at Day 43. SER-155 was well tolerated, with no drug-related serious adverse events observed. The Company is progressing plans for a next study evaluating SER-155 for the prevention of irEC in patients initiating ICI cancer therapy, which is expected to include a dose optimization component. The Company expects to submit the study design to the FDA in the first quarter of 2027.

Clinical data from the SER-155 Phase 1b study in allo-HCT and the IST in irEC, in particular the drug pharmacology translational biomarker data, along with the Company's extensive preclinical and other translational clinical data compiled over the past decade support and inform the advancement of the Company's earlier stage programs targeting I&I diseases. The Company is developing SER-603, broadly in inflammatory bowel disease ("IBD"), including ulcerative colitis ("UC"), and Crohn's disease. SER-603 is a novel, LBP candidate optimized to address disruptions in the GI microbiome and to improve GI mucosal barrier integrity through the inhibition of inflammatory bacteria and associated metabolites, the promotion of epithelial barrier integrity to reduce the translocation of inflammatory molecules and barrier inflammation, and to induce immune homeostasis through non-immunosuppressive regulatory T

cell, or T-reg, induction via T cell signaling. The Company is currently exploring potential collaborations related to I&I disease programs.

In 2025, the Company was awarded a grant from Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X") for up to $3,583, representing the Company's second CARB-X award, to support the development of an oral liquid formulation based on SER-155 strains, now referred to as SER-428, for dosing in patients who cannot take oral capsules such as intubated patients in the medical ICU, and other medically vulnerable patients at high risk of AMR infections. The Company began recognizing revenue from this grant in the third quarter of 2025. The Company has advanced development and manufacturing of SER-428 and is designing a Phase 1b open label trial in collaboration with Columbia University to evaluate this LBP candidate in medical ICU patients at high risk of infection.

The Company has built and deploys a reverse translational platform and knowledge base for the discovery and development of LBPs, and maintains extensive proprietary know-how that may be used to support future research and development efforts. This platform incorporates high-resolution analysis of human clinical data to identify microbiome biomarkers associated with disease and non-disease states; preclinical screening using human cell-based assays and in vitro/ex vivo and in vivo disease models customized for live biotherapeutics; and a strain library and associated microbiological capabilities that spans broad biological and functional breadth. This platform and knowledge base are integrated through a proprietary knowledge graph and agentic artificial intelligence, enabling rapid identification of specific microbes, microbial genes, and microbial metabolites/peptides associated with disease and the design of therapeutic consortia of bacteria for specific pharmacological properties to restructure the gut microbiome and modulate functional pathways associated with disease. In addition, the Company owns a valuable intellectual property estate related to the development and manufacture of live biotherapeutics.

On February 12, 2026, the Company announced that it implemented cost reduction actions, including reducing its workforce by approximately 30%. During the nine months ended September 30, 2026, the Company incurred approximately $914 in restructuring costs, primarily related to severance costs, of which $718 was paid in the first quarter of 2026, and the remainder of these costs were paid out in the second quarter of 2026.

Going Concern

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. As of September 30, 2026, the Company had an accumulated deficit of $1,004,021 and cash and cash equivalents of $17,528.

The Company's product candidates are in development, and will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to potential commercialization. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, or maintained, that any product candidate developed will obtain necessary government regulatory approval, or that any approved product will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales.

Primarily as a result of the costs associated with the discovery and development of novel live biotherapeutics, the Company incurred a net loss from operations of $58,332 for the nine months ended September 30, 2026. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. Based on the Company's currently available cash resources and the $12,500 Milestone Termination Payment (as defined below in Note 3, *Discontinued Operations and TSA*) received from SPN (as defined below) in October 2026, current and forecasted level of operations, and forecasted cash flows for the 12-month period subsequent to the date of issuance of these condensed consolidated financial statements, the Company will require additional funding to support its ongoing operations and meet its obligations as they come due. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they come due, and to generate profitable operations in the future. Management plans to provide for the Company's capital requirements through financing or other strategic transactions, including potential business development transactions, and selling shares under the Company's at the market equity offering. There can be no assurance that the Company will be able to access additional capital to fund operations with terms acceptable to the Company, or at all. Because certain elements of management's plans to mitigate the conditions that raised substantial doubt about the Company's ability to continue as a going concern are outside of the Company's control, including the ability to raise capital through

an equity or other financing, those elements cannot be considered probable according to Accounting Standards Codification ("ASC") 205-40, *Going Concern* ("ASC 205-40"), and therefore cannot be considered in the evaluation of mitigating factors. As a result, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for 12 months from the date these condensed consolidated financial statements are issued. The accompanying condensed consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements as of September 30, 2026 and for the three and nine months ended September 30, 2026 and 2025 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2025 included in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2025, which was filed with the SEC on March 12, 2026 (the "Annual Report").

The unaudited condensed consolidated interim financial statements have been prepared on the same basis as the audited consolidated financial statements. The condensed consolidated balance sheet at December 31, 2025 was derived from audited annual financial statements, but does not contain all of the footnote disclosures from the annual financial statements. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments which are necessary for a fair statement of the Company's financial position, results of operations, and cash flows for the periods presented. Such adjustments are of a normal and recurring nature. The results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2026.

The Company's condensed consolidated financial statements include its accounts and the accounts of its wholly owned subsidiaries. All intercompany transactions have been eliminated in consolidation. The condensed consolidated financial statements have been prepared in conformity with U.S. GAAP.

On April 21, 2025, the Company effected a 1-for-20 reverse stock split of the Company's common stock. All share and per share amounts in the financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split. The reverse stock split had no impact on the number of authorized shares or the par value of preferred and common stock. Therefore, the Company reclassified an amount equal to the reduction in the number of shares of common stock at par value to additional paid-in capital. No fractional shares were issued in connection with the reverse split, and stockholders who would otherwise be entitled to receive a fractional share instead received a cash payment equal to the fraction of a share of common stock in lieu of such fractional share. Proportionate adjustments were made to the number of shares authorized under the Company's equity incentive plans, the number of shares subject to any award or purchase right under the Company's equity incentive plans, and the exercise price or purchase price with respect to any stock option award or purchase right under the Company's equity incentive plans. See Note 7, *Common Stock and Stock-Based Awards*, for further information.

2. Summary of Significant Accounting Policies

The significant accounting policies and estimates used in preparation of the unaudited condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2025, and the notes thereto, which are included in the Annual Report. There have been no material changes to the Company's significant accounting policies during the nine months ended September 30, 2026.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amount of expenses during the reporting periods. In the unaudited condensed consolidated financial statements, the Company uses estimates and assumptions related to the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates.

Restricted Cash

The Company held restricted cash of $3,136 and $8,668 as of September 30, 2026 and December 31, 2025, respectively, which represents cash held for the benefit of the landlords for the Company's leases. As of September 30, 2026 the Company classified $2,363 of restricted cash within prepaid expenses and other current assets as the terms of the relative underlying lease is less than one

year and $773 of restricted cash as long-term on its condensed balance sheets as the terms of the underlying leases are greater than one year.

Cash, cash equivalents and restricted cash were comprised of the following (in thousands):

	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 17,528	$ 45,766
Restricted cash	3,136	8,668
Total cash, cash equivalents and restricted cash	$ 20,664	$ 54,434

Recently Adopted Accounting Pronouncements

In September 2025, the FASB issued ASU No. 2025-07, *Derivatives and Hedging and Revenue from Contracts with Customers - Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract,* which applies to all entities that enter into non-exchange-traded contracts with underlyings based on operations or activities specific to one of the parties to the contract. The guidance in ASU 2025-07 expands the scope exceptions within ASC Topic 815, *Derivatives and Hedging*, to include certain nonexchange-traded contracts with underlyings that are based on operations or activities specific to one of the parties to the contract, including research and development funding arrangements. The Company early-adopted ASU 2025-07 effective January 1, 2026, and will account for the new ASU on a prospective basis to any new contracts entered into after the effective date. The adoption of ASU 2025-07 did not have a material impact on the Company's condensed consolidated financial statements or financial statement disclosures.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses (Topic 220)*, which requires disclosure in the notes to financial statements about specific types of expenses included in the expense captions presented on the face of the statement of operations. The requirements of the ASU are effective for annual periods beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is currently evaluating the impact related to the adoption of ASU 2024-03 on its financial statement disclosures.

In December 2025, the FASB issued ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities*, which standardizes the accounting for government grants and distinguishes between a grant related to an asset and a grant related to income. The requirements of the ASU are effective for annual periods beginning after December 15, 2028, and for interim periods within those annual periods, with early adoption permitted. The requirements can be applied using a modified prospective or a modified retrospective approach. The Company does not expect the impact of ASU 2025-10 to be material to its financial statement disclosures as it is consistent with the Company's current accounting policy for government grants.

3. Discontinued Operations and TSA

On September 30, 2024, the Company completed the sale (the “Transaction”) of its VOWST microbiome therapeutic business (the “VOWST Business”), including inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of the microbiome product sold under the brand name VOWST as provided for in accordance with the terms of the Purchase Agreement (the “Product”), to Société des Produits Nestlé S.A. (“SPN”), a wholly-owned subsidiary of Nestlé S.A., and its designated affiliates (collectively, “Nestlé Health Science”) pursuant to the Asset Purchase Agreement, dated as of August 5, 2024 (the “Purchase Agreement”), by and among the Company and SPN, and a wholly-owned subsidiary of Nestlé S.A.

The Company also entered into a Transition Services Agreement (“TSA”) with Nestlé Enterprises S.A., (“NESA”), an affiliate of SPN, in connection with the Transaction, through which the Company provided certain manufacturing services until December 31, 2025, and other transition services, for the duration specified in the schedule to the TSA for each service. The Company's obligations under the TSA are now complete. For the three and nine months ended September 30, 2026 and 2025, the Company recognized $0, $0, $2,028, and $11,827 respectively, of TSA reimbursement income in other income in the Company’s condensed consolidated statements of operations and comprehensive (loss) income. For the three and nine months ended September 30, 2026 and 2025, the Company incurred $0, $0, $736, and $5,952, respectively, of expenses related to manufacturing services and $0, $0, $76, and $3,585, respectively, of TSA labor and passthrough expenses to support the transition services, including finance and accounting, information technology, human resources, operations, and other services.

For the three and nine months ended September 30, 2026 and 2025, $0, $0, $1,756, and $13,743, respectively, was billed to NESA related to transition services performed by the Company, and the Company received $0, $360, $2,212, and $90,385 from

NESA during the periods, respectively. The payments received in 2025 included the installment payment of $50,000 received in January 2025 and the installment payment of $25,000 received in July 2025 which were conditioned on the Company's material compliance with obligations under the TSA. The installment payments were recognized in Gain on sale of VOWST Business within continuing operations in the Company's condensed consolidated statements of operations and comprehensive income for the three and nine months ended September 30, 2025 as the gain was realizable.

The Company has estimated costs associated with certain accrued liabilities due to SPN - related party as a loss contingency in accordance with ASC 450, *Contingencies.* These contingent liabilities are presented as Accrued Liabilities due to SPN - related party from continuing operations on the condensed consolidated balance sheet as of September 30, 2026 and December 31, 2025 and consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Profit Sharing Payments	$ 1,701	$ 1,701
Royalties associated with the MSK Agreement	1,309	1,309
VOWST post-marketing safety surveillance study costs	268	268
Total accrued liabilities due to SPN - related party	$ 3,278	$ 3,278

The contingent liabilities accrued on the Company's condensed consolidated balance sheet are remeasured at each reporting period based on i) cash payments made by the Company to reduce the accrued liabilities due to SPN - related party and ii) revised estimates of the total remaining liabilities due to SPN - related party. For the three and nine months ended September 30, 2026 and 2025, the Company recognized a gain on sale of VOWST Business of $0, $0, $2,222, and $4,588, respectively, as a result of the change in accrued liabilities due to SPN - related party.

On June 2, 2026, the Company entered into Amendment No. 1 (the "APA Amendment") to the Purchase Agreement. Pursuant to the Purchase Agreement, SPN agreed to pay the Company certain one-time contingent milestone payments during the Milestone Period (as defined in the Purchase Agreement) if and following the first time that the worldwide annual net sales of the Product (as defined in the Purchase Agreement) reached the following thresholds: (i) a $125,000 milestone payment upon the first calendar year in which annual worldwide net sales of the Product equal or exceed $400,000 (the "Second Sales Milestone Payment"); and (ii) a $150,000 milestone payment upon the first calendar year in which annual worldwide net sales of the Product equal or exceed $750,000 (the "Third Sales Milestone Payment"). Pursuant to the Purchase Agreement, the Prepaid Milestone (as defined in the Purchase Agreement) accrued interest during the Milestone Period, which would reduce the Second Sales Milestone Payment to Seres if and when it became payable (the "Milestone Interest Payments"). Pursuant to the APA Amendment, the parties agreed to terminate SPN's obligations with respect to the Second Sales Milestone Payment, the Third Sales Milestone Payment and eliminate the Milestone Interest Payments that would have been due from the Company to SPN. In consideration for the foregoing, SPN agreed to a one-time payment to the Company of $25,000 (the "Milestone Termination Payment"), which amount is payable in two equal installments of $12,500, with the first installment paid on July 1, 2026 and the second installment paid on October 1, 2026.

As there are no conditions under which the Company would be required to repay the $25,000, or any portion of the interest that was accruing on the Prepaid Milestone under the Purchase Agreement, and there are no circumstances under which SPN would be relieved of its obligation to make this payment to the Company, the gain was considered realizable in June 2026 when the APA Amendment was signed. The Company recorded a Gain on Sale of VOWST Business within continuing operations of $25,000 during the nine months ended September 30, 2026 because the amount is fixed consideration and is no longer contingent on a future event. As of September 30, 2026 and December 31, 2025, the Company had $12,500 and $360 respectively, in accounts receivable due from SPN - related party in the Company's condensed consolidated balance sheets.

4. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Laboratory equipment	$ 21,934	$ 23,852
Computer equipment	3,423	4,058
Furniture and office equipment	2,456	4,523
Leasehold improvements	3,749	30,954
Construction in progress	861	861
	32,423	64,248
Less: Accumulated depreciation and amortization	(29,424)	(56,613)
	$ 2,999	$ 7,635

Depreciation and amortization expense was $481, $1,932, $1,044, and $3,179 for the three and nine months ended September 30, 2026 and 2025, respectively. During the three and nine months ended September 30, 2026, the Company disposed of certain assets with a cost basis of $28,670 and $31,825 and a net book value of $2,318 and $2,704, primarily related to leasehold improvements that were impaired in connection with the Termination Agreement as defined in Note 6, *Leases*, as well as assets that were returned to the landlord in connection with the Lease Amendment as defined in Note 6, *Leases*. The Company did not dispose of any assets during the three and nine months ended September 30, 2025.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Clinical and development costs	$ 386	$ 246
Manufacturing and quality costs	93	145
Payroll and employee-related costs	2,074	2,685
Facility and other	951	896
	$ 3,504	$ 3,972

6. Leases

The Company leases real estate, primarily laboratory, office and manufacturing space. The Company's leases have remaining terms ranging from less than one year to ten years. One of the Company's leases includes an option to renew, exercisable at the Company's sole discretion, with renewal terms that can extend the lease for up to ten years. The Company previously evaluated the renewal options in its leases to determine if it was reasonably certain that the renewal option would be exercised. Given the Company's current business structure, uncertainty of future growth, and the associated impact to real estate, the Company concluded that it is not reasonably certain that any renewal options would be exercised. Therefore, the operating lease assets and operating lease liabilities only contemplate the initial lease terms. All the Company's leases qualify as operating leases.

In June 2026, in order to reduce the Company's ongoing annual rent costs and facilities footprint, the Company entered into the First Amendment to Lease (the "Lease Amendment") with 101 CPD LLC (f/k/a HCP/King 101 CPD LLC), a Delaware limited liability company (the "Landlord"), which amends the Lease Agreement, dated September 22, 2021, by and between the Company and the Landlord (as amended, the "Lease"), pursuant to which the Company leases approximately 82,714 rentable square feet of office and laboratory space in Cambridge, Massachusetts.

Effective as of May 1, 2026, the Lease Amendment reduced the amount of space subject to the lease from 82,714 rentable square feet of space to 36,882 rentable square feet, extended the term of the renewal premises to December 31, 2036, and reduced the base rent the Company is obligated to pay the Landlord for the renewal premises to $79.70 per rentable square foot per year, subject to an annual adjustment of 3%. Concurrent with the execution of the Lease Amendment, the Company entered into a separate lease for the portion of the space under the Lease that was not retained (the "Early Termination Premises") with a lease term that ends on December 31, 2027. There are no ongoing legal or economic liabilities of the Company related to this lease of the Early Termination Premises apart from the termination payments described below related to the Lease Amendment. The Company accounted for the Lease Amendment and the lease of the Early Termination Premises as a single contract with two lease components, as the agreements were negotiated simultaneously.

As consideration for the Lease Amendment, the Company agreed to pay the following: (i) a $4,500 termination fee payable on the execution of the Lease Amendment, and (ii) on or before January 4, 2027, a deferred payment of $5,201 which may be satisfied either as an unconditional letter of credit or in cash, of which $1,967 represents the Company's rent obligations for the period from May 1, 2026 through December 31, 2026 and $3,234 represents an additional termination payment. Further, the Company permitted the Landlord to draw the existing letter of credit held by Landlord under the Lease equal to $6,266. Minimum lease payments total $36,763 throughout the term of the Lease Amendment, for total consideration of $50,763 inclusive of termination fees and the letter of credit draw. The Company identified two lease components, the retained space subject to the Lease Amendment, and the Early Termination Premises. Consideration was allocated to each lease component based on their relative standalone selling prices.

The Company accounted for the Lease Amendment as a modification to the existing lease and not a new contract separate from the existing contract, and accordingly decreased the associated lease liability and right-of-use asset by $11,538.

During the nine months ended September 30, 2026, the Company identified an indicator of impairment relating to the Early Termination Premises, as the Company is not planning to use the Early Termination Premises; additionally, the Company is prohibited under the lease from marketing the Early Termination Premises for sublease. The Company determined that this represents a significant adverse change in the extent in which the long-lived asset was being used. The Company concluded that the carrying value

of the Early Termination Premises, which represents a single asset group, was not recoverable as there are zero future cash flows that are expected to be generated from the assets within the asset group. The Company recognized an impairment loss of $5,807, consisting of $5,574 on the operating lease right-of-use asset and $233 on the leasehold improvements, in the nine months ended September 30, 2026. The impairment loss is disaggregated in the accompanying condensed consolidated statements of operations and comprehensive income (loss) as a separate line, impairment of long-lived assets.

On July 31, 2026, the Company entered into the Third Amendment to Lease and Termination Agreement (the "Termination Agreement") with BMR-Sidney Research Campus LLC, a Delaware limited liability company (the "Sidney Street Landlord"), the purpose of which is to effect an early termination of one of the Company's leases, reducing the Company's ongoing annual facilities costs and materially eliminating the Company's primary restoration obligations. The Termination Agreement amends the Lease Agreement, dated November 11, 2015, by and between the Company and the Sidney Street Landlord (as amended, the "Sidney Street Lease"), pursuant to which the Company leases approximately 68,636 rentable square feet of office, laboratory, and manufacturing space located at 200 Sidney Street, Cambridge, Massachusetts (the "Existing Premises").

The Termination Agreement provides for (i) effective as of August 1, 2026, the surrender by the Company to the Sidney Street Landlord of an aggregate area of approximately 21,295 rentable square feet of the Existing Premises (the "Sidney Early Termination Premises"), and (ii) the revision of the expiration date of the term of the Lease with respect to the remaining 47,341 rentable square feet of the Existing Premises (the "Renewal Premises") from January 13, 2031 to December 31, 2026. As consideration for the Termination Agreement, the Company agreed to pay the following: (i) an increase to the letter of credit held by the Sidney Street Landlord in the amount of $2,238 (for a total letter of credit of $3,638), which the Sidney Street Landlord will apply toward rent and operating expenses through the term of the Renewal Premises, (ii) on or before January 4, 2027, a termination payment of $3,850, and (iii) an equity issuance of shares of the Company's common stock valued at $500 (the "Share Issuance").

On July 31, 2026, in connection with the Share Issuance, the Company entered into a Stock Issuance Agreement (the "Stock Issuance Agreement") with the Sidney Street Landlord, pursuant to which the Company agreed to issue 103,520 shares of Common Stock (the "Shares") to the Sidney Street Landlord at a price per share of $4.83, which was the closing price of the Common Stock on the Nasdaq Global Select Market ("Nasdaq") on July 31, 2026. The Shares are registered under the Company's registration statement on Form S-3 (File No. 333-273794), pursuant to a prospectus supplement, dated July 31, 2026 and the accompanying base prospectus, dated August 15, 2023, and were freely tradeable when issued. The Stock Issuance Agreement contains customary representations and warranties of the Company and the Sidney Street Landlord and customary conditions to the share issuance.

The reduction of the lease term and associated lease payments for the Renewal Premises does not grant the Company an additional right-of-use, so it is therefore accounted for as a modification to the existing lease and not a new contract separate from the existing contract. Accordingly, the Company remeasured the lease liability to account for the remaining lease payments, inclusive of the letter of credit, the future termination payment, and the equity issuance, over the remaining lease term and decreased the associated lease liability and right-of-use asset by $18,884.

During the three months ended September 30, 2026, the Company identified an indicator of impairment relating to the Renewal Premises, as the Company fully exited the Renewal Premises concurrent with the Termination Agreement; additionally, given the reduced lease term of five months from the date the Termination Agreement was executed, the Company is unable to sublease the Renewal Premises. The Company determined that this represents a significant adverse change in the extent to which the long-lived asset was being used. The Company concluded that the carrying value of the Renewal Premises, which represents a single asset group, was not recoverable and the fair value of the asset group is zero. The Company recognized an impairment loss of $5,705, consisting of $3,654 on the operating lease right-of-use asset and $2,051 on the leasehold improvements, in the three and nine months ended September 30, 2026. The impairment loss is disaggregated in the accompanying condensed consolidated statements of operations and comprehensive income (loss) as a separate line, impairment of long-lived assets.

Concurrent with the Termination Agreement, the Company assigned its existing sublease for the Sidney Early Termination Premises to the Sidney Street Landlord. As a result, the Company concluded that the remaining straight-line sublease receivable would not be realized and recognized a loss of $469 upon termination of the sublease, which is included within other income (expense) in the accompanying condensed consolidated statements of operations and comprehensive income (loss).

The following table summarizes the presentation in the Company's condensed consolidated balance sheets of its operating leases (in thousands):

	September 30, 2026	December 31, 2025
Assets:		
Operating lease assets	$ 27,662	$ 72,483
Liabilities:		
Operating lease liabilities	$ 12,650	$ 10,390
Operating lease liabilities, net of current portion	23,122	72,576
Total operating lease liabilities	$ 35,772	$ 82,966

The following table summarizes the effect of lease costs in the Company's condensed consolidated statements of operations and comprehensive (loss) income (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease costs	$ 2,065	$ 4,781	$ 10,631	$ 14,399
Variable lease costs	887	1,745	4,040	4,708
Sublease (income) expense	287	(814)	(1,200)	(2,446)
Total lease costs	$ 3,239	$ 5,712	$ 13,471	$ 16,661

During the three and nine months ended September 30, 2026 and 2025, the Company made cash payments for operating leases of $2,584, $21,731, $4,837, and $14,552, respectively.

As of September 30, 2026, future payments of operating lease liabilities are as follows (in thousands):

	As of September 30, 2026
2026 (remaining 3 months)	$ 2,579
2027	13,693
2028	4,443
2029	3,220
2030	3,317
2031 and thereafter	22,097
Total future minimum lease payments	$ 49,349
Less: interest	(13,577)
Present value of operating lease liabilities	$ 35,772

As of September 30, 2026, the weighted average remaining lease term was 8.49 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 9.5%. As of September 30, 2025, the weighted average remaining lease term was 6.29 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 13%.

7. Common Stock and Stock-Based Awards

On April 10, 2025, at the Company's 2025 annual meeting of stockholders (the "2025 Annual Meeting"), stockholders approved an amendment to the Company's Restated Certificate of Incorporation in order to effect a reverse stock split of all outstanding shares of the Company's common stock. On April 21, 2025, the Company effected a 1-for-20 reverse stock split of its common stock. The reverse stock split had no impact on the number of authorized shares or the par value of preferred and common stock. As of the effective time of the reverse stock split, the number of shares of common stock issuable upon exercise, vesting or settlement of outstanding awards, the exercise price of all outstanding options and any stock price vesting goals with respect to any outstanding awards under the Company's equity plans (including the 2025 Plan, as defined below) was proportionately adjusted (and rounded down to the nearest whole share in the case of shares and up to the nearest whole cent in the case of exercise prices, as applicable) based on the 1-for-20 ratio. In addition, the number of shares available for future issuance and any share-based award limits under the Company's equity plans were proportionately reduced based on the 1-for-20 ratio. Trading of the Company's common stock on The Nasdaq Global Select Market commenced on a split-adjusted basis on April 22, 2025.

Additionally, at the 2025 Annual Meeting, stockholders approved the Seres Therapeutics, Inc. 2025 Incentive Award Plan (the "2025 Plan") as an amendment and restatement of the Seres Therapeutics, Inc. 2015 Incentive Award Plan (the "2015 Plan"). The

amendment, among other things, authorized the issuance of 2,230,243 shares of the Company's common stock for awards under the 2025 Plan, which includes 1,750,493 shares previously authorized for issuance under the 2015 Plan plus an increase of 479,750 shares (in each case, which amounts reflect the 1-for-20 reverse stock split), and extended the term of the 2025 Plan to March 3, 2035, the tenth anniversary of the approval of the 2025 Plan by the Company's board of directors. On July 8, 2026, at the Company's reconvened 2026 annual meeting of stockholders (the "2026 Annual Meeting"), stockholders approved an amendment and restatement of the 2025 Plan to increase the number of authorized shares available for issuance under the 2025 Plan by 900,000.

On May 21, 2021, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") to sell shares of the Company's common stock, with aggregate gross sales proceeds of up to $150,000, from time to time, through an "at the market" equity offering program ("ATM") under which Cowen acts as sales agent. During the three and nine months ended September 30, 2026, the Company sold 113,643 and 371,725 shares of common stock under the Sales Agreement, at an average price of approximately $7.45 and $8.37 per share, respectively, raising aggregate net proceeds of approximately $741 and $2,856 after deducting an aggregate commission of approximately 3% and other issuance costs. During the nine months ended September 30, 2025, the Company sold 54,806 shares of common stock under the Sales Agreement, at an average price of approximately $18.60 per share, raising aggregate net proceeds of approximately $996 after deducting an aggregate commission of approximately 3% and other issuance costs. On August 13, 2026, the Company entered into a Sales Agreement (the "2026 Sales Agreement") with TD Securities (USA) LLC ("TD Cowen") to sell shares of the Company's common stock, with aggregate gross sales proceeds of up to $100,000, from time to time, through an at the market equity offering program under which TD Cowen acts as sales agent. During the three months ended September 30, 2026, no shares were sold under the 2026 Sales Agreement.

Stock Options

The following table summarizes the Company's stock option activity since December 31, 2025:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2025	1,124,208	$ 68.07	7.17	$ 228
Granted	777,579	$ 8.69		
Exercised	—			
Forfeited	(191,467)	$ 80.95		
Outstanding as of September 30, 2026	1,710,320	$ 39.63	7.84	$ —
Vested or expected to vest as of September 30, 2026	1,710,320	$ 39.63	7.84	$ —
Options exercisable as of September 30, 2026	659,524	$ 83.60	6.06	$ —

The weighted average grant date fair value of stock options granted during the three and nine months ended September 30, 2026 and 2025 was $6.34, $7.43, $10.34, and $13.30 per share, respectively.

During 2024, the Company granted stock options to certain executives for the purchase of an aggregate of 127,500 shares of common stock. These awards will vest only to the extent that the 30-day trailing simple average public market closing price of the Company's common stock reaches certain price thresholds. These awards have an exercise price of $22.00 and vest and become exercisable when the market conditions are satisfied or, if later, on the first anniversary of the grant date. These awards expire 10 years from the date of grant. The fair value of these market-based stock options was estimated using a Monte Carlo valuation method. During the three and nine months ended September 30, 2026 and 2025, the Company recognized $83, $331, $190 and $451, respectively, of compensation expense related to these awards.

Restricted Stock Units

The Company has granted restricted stock units with service-based vesting conditions ("RSUs") and restricted stock units with performance-based vesting conditions ("PSUs"). RSUs and PSUs represent the right to receive shares of common stock upon meeting specified vesting requirements. Restricted stock units may not be sold or transferred by the holder and vest according to the vesting conditions of each award. RSUs generally vest over four years, with 25% vesting after one year, and the remaining 75% vesting quarterly over the next 3 years, subject to continued service to the Company through the applicable vesting date. PSUs vest according to the performance requirements of the awards, generally when the Company has determined that the specified performance targets have been achieved.

The following table summarizes the Company's RSU and PSU activity since December 31, 2025:

	Number of Shares		Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2025	24,150	$	57.31
Granted	173,385	$	8.74
Vested	(157,551)	$	13.32
Forfeited	(29,278)	$	10.76
Unvested restricted stock units as of September 30, 2026	10,706	$	45.35

During the three and nine months ended September 30, 2026 and 2025, the Company granted 0, 173,385, 68,596, and 79,846 RSUs, respectively. During the three and nine months ended September 30, 2026 and 2025, the Company did not grant any PSUs.

In February 2026, the Company issued retention awards to non-executive employees of the Company in the form of RSUs covering 173,385 shares of common stock with a grant date fair value of $8.74 per share. The retention RSUs were fully vested on September 30, 2026 subject to the employee's continued employment with the Company through such date. The compensation expense associated with these awards is being recognized ratably over the vesting period. For the three and nine months ended September 30, 2026, the Company recognized $530 and $1,271 in compensation expense with respect to the retention RSUs.

Stock-based Compensation Expense

The Company recorded stock-based compensation expense in the following expense categories of its condensed consolidated statements of operations and comprehensive (loss) income (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development expenses	$ 833	$ 1,076	$ 2,327	$ 3,417
General and administrative expenses	1,026	1,406	3,037	4,224
	$ 1,859	$ 2,482	$ 5,364	$ 7,641

8. Net (Loss) Income per Share

Basic and diluted net (loss) income per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Basic Earnings Per Share:				
Numerator:				
Net (loss) income	$ (16,286)	$ 8,204	$ (31,618)	$ 21,031
(Loss) income attributable to common stockholders - basic	$ (16,286)	$ 8,204	$ (31,618)	$ 21,031
Denominator:				
Weighted-average shares outstanding - basic	9,982,031	8,758,692	9,764,763	8,735,418
Net (loss) income per share attributable to common stockholders - basic	$ (1.63)	$ 0.94	$ (3.24)	$ 2.41
Diluted Earnings Per Share:				
Numerator:				
Net (loss) income	$ (16,286)	$ 8,204	$ (31,618)	$ 21,031
(Loss) income attributable to common stockholders - diluted	$ (16,286)	$ 8,204	$ (31,618)	$ 21,031
Denominator:				
Weighted-average shares outstanding - basic	9,982,031	8,758,692	9,764,763	8,735,418
Dilutive impact from:				
Stock options to purchase common stock	—	2,139	—	—
Unvested restricted stock units	—	8,990	—	9,377
Shares issuable under employee stock purchase plan	—	1,698	—	2
Weighted-average shares outstanding - diluted	9,982,031	8,771,519	9,764,763	8,744,797
Net (loss) income per share applicable to common stockholders - diluted	$ (1.63)	$ 0.94	$ (3.24)	$ 2.40
Anti-dilutive potential common stock equivalents excluded from the calculation of net (loss) income per share:				
Stock options to purchase common stock	1,710,320	1,188,732	1,710,320	1,188,732
Unvested restricted stock units	10,706	100,824	10,706	100,824
Shares issuable under employee stock purchase plan	1,851	1,256	623	423
Warrants to purchase common stock	32,379	32,379	32,379	32,379

The Company's potential dilutive securities include stock options, unvested restricted common stock and shares issuable under the 2015 Employee Stock Purchase Plan. The effect of dilutive securities was calculated using the treasury stock method. The anti-dilutive potential common stock equivalents for the three and nine months ended September 30, 2026 were excluded from the computation of diluted net loss per share attributable to common stockholders because those stock options to purchase common stock, restricted stock units, and shares issuable under employee stock purchase plan had an anti-dilutive impact as the Company reported a net loss from continuing operations attributable to common stockholders for those periods. The anti-dilutive potential common stock equivalents for the three and the nine months ended September 30, 2025 were excluded from the computation of diluted net income per share attributable to common stockholders because those stock options to purchase common stock and restricted stock units had an anti-dilutive impact due to the assumed proceeds per share using the treasury stock method being greater than the average fair value of the Company's common shares for those periods. For that same period, the warrants to purchase common stock were excluded because the exercise price of the warrants is greater than the average fair value of the Company's common shares.

9. Commitments and Contingencies

Leases

Refer to Note 6, *Leases*, for discussion of the commitments associated with the Company's lease portfolio.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of September 30, 2026 or December 31, 2025.

Legal Contingencies

The Company accrues a liability for legal contingencies when it believes that it is both probable that a liability has been incurred and that the Company can reasonably estimate the amount of the loss. The Company reviews these accruals and adjusts them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and the views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in the Company's accrued liabilities will be recorded in the period in which such determination is made.

In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, the Company will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, the Company will provide disclosure to that effect. The Company expenses legal costs as they are incurred.

The Company did not accrue any liabilities related to legal contingencies in its condensed consolidated financial statements as of September 30, 2026 or December 31, 2025.

10. Income taxes

The Company did not provide for any income taxes in its condensed consolidated statement of operations and comprehensive (loss) income for the three and nine months ended September 30, 2026 and 2025. Management considered the Company's history of cumulative net losses incurred since inception, its early stage of development of its product candidates, and its projection of book and tax losses for the year ending December 31, 2026. Based on its evaluation of the positive and negative evidence bearing upon its ability to realize its deferred tax assets, the Company determined that it is more likely than not that it will not realize such benefits. Accordingly, the Company has recorded a full valuation allowance against its deferred tax assets as of September 30, 2026 and December 31, 2025, and has not recorded any income taxes for the three and nine months ended September 30, 2026 and 2025. Management reevaluates the positive and negative evidence at each reporting period.

11. Related Party Transactions

As described in Note 3, *Discontinued Operations and TSA*, in September 2024, the Company sold the VOWST Business, including inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of VOWST, to SPN, and SPN assumed certain liabilities from the Company. As consideration for the Transaction, the Company received an upfront cash payment of $139,788, which consisted of $100,000, less $17,857 owed by the Company to an affiliate of SPN under the prior license agreement between the Company and the SPN affiliate, less approximately $2,355 in satisfaction of fees due under the Bacthera Manufacturing Agreement; plus a prepayment of the $60,000 milestone payment tied to the achievement of worldwide annual net sales of VOWST of $150,000; plus an equity investment of $15,000 based on the Securities Purchase Agreement pursuant to which SPN purchased 714,285 shares of common stock at a purchase price of $21.00 per share.

As of September 30, 2026 and December 31, 2025, there was $3,278 included in Accrued Liabilities due to SPN - related party on the Company's condensed consolidated balance sheet, which represents amounts due to SPN pursuant to the Purchase Agreement, which are further described in Note 3, *Discontinued Operations and TSA*. During the three and nine months ended September 30, 2026 and 2025, the Company paid $0, $0, $6,284, and $7,593, to SPN related to the Purchase Agreement during the periods, respectively.

As described in Note 3, *Discontinued Operations and TSA*, the Company entered into the TSA with NESA, an affiliate of SPN, in connection with the Transaction, through which the Company provided certain manufacturing services until December 31, 2025, and other transition services, for the duration specified in the schedule to the TSA for each service. For the three and nine months ended September 30, 2026 and 2025, the Company recognized $0, $0, $2,028, and $11,827, respectively, of TSA

reimbursement income in other income in the Company's condensed consolidated statements of operations and comprehensive (loss) income. For the three and nine months ended September 30, 2026 and 2025, the Company incurred $0, $0, $736, and $5,952, respectively, of expenses related to manufacturing services and $0, $0, $76, and $3,585, respectively, of TSA labor and passthrough expenses to support the transition services, including finance and accounting, information technology, human resources, operations, and other services.

During the three and nine months ended September 30, 2026 and 2025, $0, $0, $1,756, and $13,743, respectively, was billed to NESA related to transition services performed by the Company, and the Company received payments of $0, $360, $2,212, and $90,385, respectively, related to transition services performed. The payments received in 2025 included the installment payment of $50,000 received in January 2025 and the second installment payment of $25,000 received in July 2025 which were conditioned on the Company's material compliance with obligations under the TSA. As of September 30, 2026 and December 31, 2025, the Company had $12,500 and $360, respectively, in accounts receivable due from SPN - related party, and $0 and $169 included in prepaid expenses and other current assets, respectively, relating to the sale of certain manufacturing and laboratory equipment, in the Company's condensed consolidated balance sheets.

As described in Note 3, *Discontinued Operations and TSA,* the Company entered into the APA Amendment with SPN pursuant to which the parties agreed to terminate SPN's obligations with respect to the Second Sales Milestone Payment, the Third Sales Milestone Payment and eliminate the Milestone Interest Payments that would have been due from the Company to SPN. In consideration for the foregoing, SPN agreed to a one-time payment to the Company of $25,000 (the "Milestone Termination Payment"), which amount is payable in two equal installments of $12,500, with the first installment paid on July 1, 2026 and the second installment paid on October 1, 2026. The Company recorded a Gain on Sale of VOWST Business within continuing operations and the corresponding receivable due from SPN of $25,000 during the three months ended June 30, 2026 because the amount is fixed consideration and is no longer contingent on a future event.

12. Segment Reporting

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions, and thus reports as a single reportable segment. The Company's interim Chief Executive Officer, who is the Chief Operating Decision Maker ("CODM"), manages and allocates resources to the operations of the Company on a total company basis by assessing the overall level of resources available and how to best deploy these resources across functions and research and development projects that are in line with the Company's long-term company-wide strategic goals. The CODM uses the Company's consolidated net income (loss) to monitor actual results versus the budget in assessing segment performance and the allocation of resources. The measure of segment assets is reported on the consolidated balance sheets as total assets.

The Company's reportable segment net (loss) income for the three and nine months ended September 30, 2026 and 2025, consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Grant revenue	$ 593	$ 351	$ 1,687	$ 351
Significant segment expenses:				
Live biotherapeutics platform	$ 2,297	$ 6,165	$ 13,705	$ 17,096
SER-155	282	1,220	1,028	2,841
R&D personnel-related (including stock-based compensation)	2,732	5,229	12,332	17,431
G&A personnel-related (including stock-based compensation)	1,964	3,863	7,926	11,761
Professional fees	1,753	2,035	4,909	7,370
Facility-related and other	1,731	3,578	7,744	12,486
Impairment of long-lived assets	5,705	—	11,512	—
Gain on sale of VOWST Business (2)	—	(27,222)	(25,000)	(79,588)
Other segment expense (income) (1)	415	(2,721)	(851)	(10,077)
Net (loss) income	$ (16,286)	$ 8,204	$ (31,618)	$ 21,031

[1] Other segment expense (income) includes manufacturing services expenses, research and development expenses on early stage programs, interest income and other expense (income), net.

[2] See Note 3, *Discontinued Operations and TSA*, for further details.

13. Subsequent Events

On October 22, 2026, Marella Thorell resigned from her positions as Executive Vice President and Chief Financial Officer of the Company, effective November 15, 2026 (the “Effective Date”). In connection with her resignation, on November 2, 2026, the Company and Ms. Thorell entered into an advisory agreement (the "Advisory Agreement") under which Ms. Thorell will provide advisory services to the Company from her resignation through March 31, 2027.

As of the Effective Date, the Board has designated Richard Kender, the Company’s Executive Chair and Interim Chief Executive Officer and principal executive officer, to serve as the Company’s principal financial officer and principal accounting officer. Mr. Kender will continue to serve as the Company’s Executive Chair and Interim Chief Executive Officer and principal executive officer, and he will not receive any additional compensation for his role as interim principal financial officer and principal accounting officer during this period.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, such as statements regarding our plans, objectives, expectations, intentions and projections, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.

On April 21, 2025, we effected a 1-for-20 reverse stock split of our common stock. All shares of our common stock, stock-based instruments, and per-share data included in this Quarterly Report on Form 10-Q have been retroactively adjusted as though the reverse stock split had been effected prior to all periods presented.

Overview

We are a clinical-stage company focused on improving patient outcomes in medically compromised populations, including oncology patients and those suffering from inflammatory and immune, or I&I, diseases through discovery and development of novel live biotherapeutic product, or LBP, candidates. We led the successful development and approval of VOWST, the first FDA-approved orally administered microbiome biotherapeutic and a Breakthrough Therapy designated drug, which was sold to Société des Produits Nestlé S.A., or SPN, and with certain of its affiliates, collectively, Nestlé Health Science, in September 2024. We have established field-leading capabilities and platforms that are powered by best-in-field human data sets to advance a portfolio of products that can uniquely address diseases by targeting host pathways that are modulated by microbes in the human body, and, in particular, diseases associated with mucosal epithelial barrier-immune interface targets. We believe clinical and nonclinical data across our programs support the development of LBPs to address unmet medical needs in oncology that can lead to interruption to patients' cancer treatment and/or mortality (by targeting the prevention and treatment of a broad swath of infection risks faced by cancer patients and by treating irEC), and to treat I&I diseases. Our pipeline consists of SER-155, SER-603, SER-428, and SER-147, as well as other potential candidates in earlier development.

We are designing LBP candidates to modulate host function to protect and improve mucosal epithelial barrier integrity, induce immune homeostasis and tolerance, and prevent the colonization and overgrowth of pathogens in the gastrointestinal, or GI, tract. We believe that the scientific and clinical data from the development of VOWST (our then product candidate SER-109 program) and the data from the SER-155 Phase 1b study in allo-HCT and the SER-155 IST in irEC (both further described below) validate our novel therapeutic approach to address unmet medical needs in oncology that can lead to interruption to patients' cancer treatment and/or mortality, and to treat I&I diseases.

In the context of preventing infection for patients undergoing allo-HCT for hematological cancer, we believe that our technology may be replicable across different bacterial pathogens with the potential to develop live biotherapeutics to protect a range of medically compromised patients at risk of antimicrobial resistance, or AMR, infections and bloodstream infections, or BSIs, that can result from a compromised mucosal epithelial barrier and that can be a major cause of mortality. SER-155, our most advanced LBP candidate, is an investigational, oral, live biotherapeutic designed to decolonize GI pathogens, improve GI mucosal epithelial barrier integrity, and induce immune homeostasis to prevent bacterial BSIs, including those that can harbor antimicrobial resistance, as well as other pathogen-associated negative clinical outcomes in patients undergoing allogeneic hematopoietic stem cell transplantation, or allo-HCT. In our placebo-controlled Phase 1b study of SER-155 in allo-HCT, SER-155 was associated with a 77% relative risk reduction in bacterial BSIs and a significant reduction in systemic antibiotic exposure as well as a lower incidence of febrile neutropenia, as compared to placebo through day 100 post HCT. SER-155 was generally well tolerated, with no observed treatment-related serious adverse events. Drug pharmacology data demonstrated that SER-155 significantly promoted mucosal epithelial barrier integrity and had a positive impact on biomarkers of systemic inflammation and immune homeostasis. In November 2026, we announced that results from our Phase 1b clinical study of SER-155 in adults undergoing allo-HCT were published in *Nature Medicine*, marking an important milestone for the program and providing recognition of the innovative science being advanced by the Company. Following advancement of key startup activities for the SER-155 Phase 2 study in allo-HCT, including the submission of a final protocol to the FDA in January 2026, study site evaluation and qualification with our CRO, and manufacturing of drug substance, we have paused additional investment in that program while continuing to seek funding for the Phase 2 study.

SER-155 is also being developed to prevent irEC, with the aim of enabling patients to continue their ICI cancer therapy and avoid the need for immunosuppressive steroid treatment. irEC is among the most frequent and severe immune-related adverse events, or irAEs, in recipients of immune checkpoint inhibitor, or ICI, therapy and can be observed in up to 50% of ICI patients, with rates varying based on cancer drug and treatment regimen. Moderate to severe (Grade 2-3) irEC occurs in approximately 25% of all ICI therapy recipients in the United States. Clinical guidelines for patients who experience Grade 2 or higher irEC require treatment, which could include halting of ICI cancer treatment and initiating a systemic immunosuppressive corticosteroid, a biologic, or both, which are associated with clinically meaningful toxicities and other negative consequences, including systemic immunosuppression, increased infection risk, metabolic complications, and potential interference with cancer treatment. In 2026, it is estimated that there are a total of 300,000 patients on ICI cancer therapy in the United States, and this figure is increasing as ICI are being used across

multiple cancer types, in earlier intervention and in combination with other cancer therapies. ICIs can cause a wide range of irAEs with links to T cell biology and epithelial barrier inflammation, both of which are biological functions shown in our preclinical and clinical pharmacology data to be positively impacted by SER-155.

SER-155 was evaluated in 15 patients with moderate-to-severe irEC through an investigator-sponsored trial, or IST, with Memorial Sloan Kettering Cancer Center, an institution with whom we have had a decade-long collaboration. Top-line data from the IST showed that 80% of SER-155 recipients achieved an immunosuppressive-free clinical response of diarrhea (a primary symptom of irEC) at Day 15, which met the primary endpoint, defined as at least a 1-grade improvement in diarrhea symptoms without immunosuppressive therapy (i.e., a corticosteroid and/or biologic immunomodulator drug). All 12 participants with immunosuppressive-free clinical response at Day 15 had the same, or better, diarrhea grade at Day 43. SER-155 was well tolerated, with no drug-related serious adverse events observed. In addition, drug pharmacology translational biomarkers of gastrointestinal inflammation (fecal calprotectin) and of mucosal epithelial barrier integrity (fecal albumin), which were elevated in participants at baseline, prior to SER-155 dosing, both showed decreases post SER-155 treatment, with statistically significant reductions achieved by Day 43, reflecting improvement in two mechanistically linked dimensions of irEC disease. Participants in the study were on a wide range of ICI types, including PD-1 inhibitors (Keytruda®, Opdivo®, Zynyz®), PD-L1 inhibitors (Imfinzi®, Bavencio®), CTLA-4 inhibitors (Yervoy®, Imjudo®), LAG-3 inhibitor (Opdualag®), and combinations thereof.

We believe there remains a significant unmet need for systemic immunosuppressive-free therapeutic approaches that reduce gastrointestinal inflammation and diarrhea and may allow patients who develop irEC to avoid disruption of their life-saving ICI cancer treatment and the promising study results support continued development of SER-155 for irEC patients.

We plan to advance SER-155 into a next study in irEC evaluating prophylactic oral administration and dose optimization in patients initiating ICI cancer therapy. The prevention approach aims to reduce incidence of irEC, keep patients on ICI therapy and avoid immunosuppressive irEC treatments. The study is being designed in consultation with leading oncologists and irEC experts. As part of the development program, we intend to engage with FDA to discuss study design and potential endpoints including incidence of irEC (all grades), ICI administration and safety. In addition, we intend to seek feedback from FDA on our plans to optimize dosing for prophylaxis, which could include a healthy volunteer study component or a dosing lead-in element, the results of which are expected to inform the prophylactic dosing course before initiating dosing in the broader ICI population. We expect to submit the study design to the FDA in the first quarter of 2027. We are also engaging with potential partners as we evaluate next steps for the development of SER-155 in irEC.

We have meaningfully advanced over the past decade our scientific understanding of how microbes in the GI functionally modulate pathways at the mucosal epithelial barrier-immune interface that are associated with inflammatory and immune-related disease. The clinical data from our SER-155 Phase 1b study in allo-HCT and the IST in irEC, in particular the drug pharmacology translational biomarker data, along with our extensive preclinical and translational clinical data compiled over the past decade support and inform the advancement of our earlier stage programs targeting I&I diseases and our current strategy continues to prioritize these indications. We are developing SER-603, broadly in inflammatory bowel disease, or IBD, including ulcerative colitis, or UC, and Crohn's disease. SER-603 is a novel, LBP candidate optimized to address disruptions in the GI microbiome and to improve GI mucosal epithelial barrier integrity through the inhibition of inflammatory bacteria and associated metabolites, the promotion of epithelial barrier integrity to reduce the translocation of inflammatory molecules and barrier inflammation, and to induce immune homeostasis through non-immunosuppressive regulatory T cell, or T-reg, induction via T cell signaling. We believe that our LBPs could represent a non-immunosuppressive treatment option for I&I diseases that are linked to colitis and could broadly address immune therapy toxicities, both of which represent significant unmet medical needs and potential commercial opportunities. We are currently exploring potential collaborations related to those I&I disease programs.

We believe that SER-155 and other cultivated live biotherapeutic candidates could be developed in additional patient populations in which mucosal epithelial barrier compromise is implicated. For example, in bloodstream and AMR infections, there are numerous medically compromised patients beyond allo-HCT, including autologous-HCT patients, cancer patients with neutropenia, chimeric antigen receptors therapy, or CAR-T, recipients, individuals with chronic liver disease, or CLD, solid organ transplant recipients, as well as patients in the intensive care unit, or ICU, and long-term acute care facilities. In 2025, we received a non-dilutive award from CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) for up to $3.6 million, representing our second CARB-X award, to support the development of an oral liquid formulation based on SER-155 strains, now referred to as SER-428, for dosing in patients who cannot take oral capsules such as intubated patients in the medical ICU, and other medically vulnerable patients at high risk of AMR infections. We have advanced development and manufacturing of SER-428 and are designing a Phase 1b open label trial in collaboration with Columbia University to evaluate this LBP candidate in medical ICU patients at high risk of infection. Additionally, we continue to develop another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream and spontaneous bacterial peritonitis, or SBP, infections in patients with metabolic disease, including CLD. We continue to leverage microbiome pharmacokinetic and pharmacodynamic data from across our clinical and preclinical portfolios, using our reverse translational development platform to prioritize future drug targets and to identify opportunities for monotherapy treatment and in combination with existing therapies across various indications, including inflammatory and immune diseases, cancer, and metabolic diseases.

We have built and deployed a reverse translational platform and knowledge base for the discovery and development of live biotherapeutics and maintain extensive proprietary know-how that may be used to support future research and development efforts. This platform incorporates high-resolution analysis of human clinical data to identify microbiome biomarkers associated with disease and non-disease states; preclinical screening using human cell-based assays and in vitro/ex vivo and in vivo disease models customized for live biotherapeutics; and a strain library and associated microbiological capabilities that span broad biological and functional breadth. This platform and knowledge base are integrated through a proprietary knowledge graph and agentic artificial intelligence, enabling rapid identification of specific microbes, microbial genes, and microbial metabolites/peptides associated with disease and the design of therapeutic consortia of bacteria for specific pharmacological properties to restructure the gut microbiome and modulate functional pathways associated with disease. In addition, we own a valuable intellectual property estate related to the development and manufacture of live biotherapeutics.

Since our inception in October 2010, we have devoted substantially all of our resources to developing our programs, platforms, and technologies, building our intellectual property portfolio, developing our supply chain, business planning, raising capital and providing general and administrative support for these operations.

Our product candidates are in early-stage clinical or preclinical development. Our ability to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Since our inception, we have incurred significant operating losses. Our net loss from operations was $58.3 million for the nine months ended September 30, 2026. As of September 30, 2026, we had an accumulated deficit of $1,004.0 million.

We plan to focus our investment in the near-term on advancing our early-stage live biotherapeutic candidates, including advancing IND-enabling studies for SER-603, evaluating the next stage of development for SER-155 in irEC, and, subject to receiving additional funding, progressing the development of SER-155 into a Phase 2 study in allo-HCT. Our expenses may increase in connection with these future activities. See "Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—*We are a clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.*"

In addition, if we obtain marketing approval for any of our product candidates, we expect to incur costs related to product manufacturing and commercialization, including marketing, sales and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company.

As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of business development transactions including collaborations with third parties, public or private equity or debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of factors such as the impacts of pandemics, increases in inflation rates, interest rates and tariffs. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. Our inability to raise capital or secure a partnership as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

As of September 30, 2026, we had cash and cash equivalents totaling $17.5 million. Based on our currently available cash resources, the $12.5 million Milestone Termination Payment received from SPN in October 2026, and considering our future operating plans, we anticipate that we will require additional funding following the first quarter of 2027. In accordance with applicable accounting standards, we evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within 12 months after the date of the issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. In performing this analysis, we excluded certain elements of our operating plan that cannot be considered probable of occurring. Under the applicable accounting standards, any future transactions or equity issuances cannot be considered probable, as these events are outside our control. Accordingly, management has concluded that substantial doubt exists about our ability to continue as a going concern for 12 months from the date the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q are issued. See "Risk Factors— Risks Related to Our Financial Position and Need for Additional Capital —*We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern*."

We continue our efforts to obtain capital and other resources to support further development of SER-155 and our broader portfolio of live biotherapeutic product candidates with applications for inflammatory diseases. We are evaluating a range of potential deal structures that we believe could leverage our live biotherapeutics expertise and success, as demonstrated by bringing VOWST from early development through FDA approval.

On February 12, 2026, we announced that we implemented cost reduction actions, including reducing our workforce by approximately 30%. During the nine months ended September 30, 2026, we incurred approximately $0.9 million in restructuring costs, primarily related to severance costs, of which $0.7 million was paid during the first quarter of 2026, and the remainder was paid out in the second quarter of 2026.

On June 5 and August 5, 2026, we announced that we amended two of our leases for a portion of our space in Cambridge, Massachusetts, under which we reduced our leased space, rental rate and facility operating expenses. The restructured leases are expected to materially reduce our ongoing annual facility-related costs and long-term obligations. On July 31, 2026, we entered into the Third Amendment to Lease and Termination Agreement with BMR-Sidney Research Campus LLC, the purpose of which was to effect an early termination of our lease at 200 Sidney Street, Cambridge, Massachusetts, reducing our ongoing annual facilities costs and materially eliminating our primary restoration obligations. Refer to Note 6, *Leases*, included elsewhere in this Quarterly Report on Form 10-Q for more information.

Our Product Pipeline

Addressing unmet medical needs in oncology patients

Treatment of Immune checkpoint-related enterocolitis (irEC)

SER-155 for irEC patients

We have been collaborating with Memorial Sloan Kettering Cancer Center for over a decade on the impact of the GI microbiome on immune related diseases and cancer; recently this long-standing collaboration included a single arm, open-label Phase 1b investigator-sponsored trial, or IST, evaluating SER-155 as a potential treatment in irEC. The study evaluated SER-155 in 15 patients with moderate-to-severe (Grade 2- 3) irEC, which affects approximately 25% of all ICI therapy recipients in the United States. Clinical guidelines for patients who experience Grade 2 or higher irEC require treatment, which could include halting of ICI cancer treatment and initiation of systemic immunosuppressive corticosteroids, which are associated with clinically meaningful toxicities and other negative consequences, including systemic immunosuppression, increased infection risk, metabolic complications, and potential interference with cancer treatment. There remains a significant unmet need for systemic, immunosuppressive-free therapeutic approaches that reduce gastrointestinal inflammation and diarrhea and may allow patients who develop irEC to avoid disruption of their life-saving ICI cancer treatment. Participants in the study were on a wide range of ICI types, including PD-1 inhibitors (Keytruda®, Opdivo®, Zynyz®), PD-L1 inhibitors (Imfinzi®, Bavencio®), CTLA-4 inhibitors (Yervoy®, Imjudo®), LAG-3 inhibitor (Opdualag®), and combinations thereof.

In July 2026, we reported initial clinical results, including preliminary safety, efficacy, pharmacology, and exploratory biomarker data. Top-line data from the IST showed that 80% of SER-155 recipients, or 12 of 15 participants, achieved an immunosuppressive-free clinical response of diarrhea (a primary symptom of irEC) at Day 15, which met the primary endpoint, defined as at least a 1-grade improvement in diarrhea symptoms without immunosuppressive therapy (i.e., a corticosteroid and/or biologic immunomodulator drug). Notably, 8 of these 12 responders (67%) achieved greater than or equal to a 2-grade improvement in diarrhea symptoms without immunosuppressive therapy at Day 15. At Day 15, 5 of 15 participants (33%) achieved immunosuppressive-free complete clinical remission, defined as total resolution of diarrhea symptoms to Grade 0, without immunosuppressive therapy. At Day 43, 5 of 15 participants (33%) maintained immunosuppressive-free clinical response, and, notably, 2 of 15 participants (13%) maintained immunosuppressive-free complete clinical remission. All 12 participants with immunosuppressive-free clinical response at Day 15 had the same, or better, diarrhea grade at Day 43. As noted, 5 maintained immunosuppressive-free clinical response at Day 43. The other 7 were treated with non-systemically acting, gastrointestinal-targeted immunosuppressives after Day 15. SER-155 was generally well tolerated through Day 43, with no safety concerns identified, consistent with the outcome in Seres' Phase 1b study of SER-155 in participants undergoing allo-HCT. There were no serious adverse events assessed as related to SER-155 and no bloodstream infections reported in the study through Day 43. Two participants experienced 2 non-serious adverse events each, assessed as possibly related to vancomycin and SER-155. All 4 adverse events were moderate in severity and were resolved. SER-155 bacterial strain engraftment (a measure of drug pharmacokinetics and strain growth in the gastrointestinal tract) was robust, with the majority of SER-155 strains observed across the study participants, and with kinetics, magnitude, and durability comparable to that observed in our prior clinical studies.

Biomarker data also supported that SER-155 was functioning as designed. At baseline, participants in the study showed evidence of epithelial barrier disruption and severe gastrointestinal inflammation as evidenced in the biomarkers fecal albumin and fecal calprotectin respectively. Fecal albumin is a biomarker that indicates protein leakage from the bloodstream into the gut lumen and provides direct evidence of mucosal epithelial barrier compromise. Fecal calprotectin is a well-established clinical biomarker of immune activation that indicates the presence of activated neutrophils in the intestinal mucosa. At study entry participants had elevated fecal albumin and calprotectin levels that are characteristic of individuals with colitis. Following SER-155 treatment, both albumin and calprotectin biomarkers show early, durable, and concordant reductions over time with significant reductions in both measures achieved by Day 43, reflecting consistent improvement across two mechanistically linked dimensions of irEC disease. These biomarker improvements were directionally consistent with the clinical observations and provide additional support for SER-155's potential biologic activity in this setting. Importantly, the pharmacological and translational results suggest that SER-155 may act on core disease-relevant biology rather than simply produce a symptomatic effect. We believe the drug pharmacology data provide supportive evidence of our live biotherapeutic candidates operating as designed to repair the mucosal epithelial barrier and reduce gastrointestinal inflammation, which supports possible expansion into multiple other inflammatory and immune diseases.

We believe data from this IST further supports the potential for live biotherapeutics to address a significant unmet need among the large population of cancer patients receiving ICIs for systemic immunosuppressive-free therapeutic approaches that have the potential to reduce gastrointestinal inflammation and diarrhea and may allow patients who develop irEC to avoid disruption of their life-saving ICI cancer treatment. We plan to advance SER-155 into a next study in irEC evaluating prophylactic oral administration and dose optimization in patients initiating ICI cancer therapy. The prevention approach aims to reduce incidence of irEC, keep patients on ICI therapy and avoid immunosuppressive irEC treatments. The study is being designed in consultation with leading oncologists and irEC experts. As part of the development program, we intend to engage with FDA to discuss study design and potential endpoints including incidence of irEC (all grades), ICI administration, and safety. In addition, we intend to seek feedback from FDA on our plans to optimize dosing for prophylaxis, which could include a healthy volunteer study component or a dosing lead-in element, the results of which are expected to inform the prophylactic dosing course before initiating dosing in the broader ICI population. We expect to submit the study design to the FDA in the first quarter of 2027.

Infection Risk Reduction

Oncology patients are particularly vulnerable to risk of infection due to their cancer treatment and conditioning procedure as well as compromised immune system. We believe that the scientific and clinical data from our VOWST program (our then product candidate SER-109 program) validate our novel approach of using live biotherapeutics to decolonize pathogens and improve mucosal epithelial barrier integrity, resulting in reduced rate of infections in medically compromised patients. Data from the ECOSPOR III and ECOSPOR IV Phase 3 trial published in the *New England Journal of Medicine* (Feuerstadt et al., 2022) and *Journal of the American Medical Association* (Sims et al., 2023) suggest that live biotherapeutics have the potential to restructure the gut microbiome and shift the gut metabolic landscape. Additional data show that VOWST rapidly reduced the abundance of bacteria associated with common antibiotic resistance genes, or ARGs, and reduced ARG abundance in the gut (Straub et al., 2023). Collectively, we believe these data suggest the potential for live biotherapeutics to prevent the colonization and overgrowth of pathogens that can establish in the gut and ultimately to reduce infections. We believe that reducing pathogen colonization in the GI and improving GI epithelial barrier integrity to reduce the risk of infection may be replicable in a range of medically compromised patients, protecting them from infections and resulting downstream clinical sequelae.

We believe this approach may also enable us to reduce AMR, which the World Health Organization declared as a top ten global public health threat facing humanity, and with estimates that yearly deaths may reach 10 million by 2050, putting mortality due to AMR on par with deaths due to cancer. Recently, two manuscripts were published in *Nature Medicine* (Bryant et al. 2026) and the *Journal of Infectious Diseases* (Bryant et al. 2025) highlighting new insights into the functional mechanism and clinical impact of VOWST. The *Nature Medicine article*, titled “The impact of an oral purified microbiome therapeutic on the GI microbiome”, confirmed our pharmacological hypotheses from earlier VOWST studies, with higher VOWST dosing associated with enhanced pharmacokinetics, as assessed by faster and more robust therapeutic species engraftment in the gut. Treatment also significantly altered the composition of the intestinal microbiome and microbe-associated metabolites, including decreased primary and increased secondary bile acids, as well as elevated short- and medium-chain fatty acids, functional changes that inhibit C. difficile spore germination and vegetative growth. Further, in vitro analyses confirmed that VOWST batches induced production of these metabolites that disrupt C. difficile life cycle and growth. Collectively, these findings support VOWST’s role in restoring microbe-associated metabolic functions critical to preventing CDI recurrence. A complementary publication in the *Journal of Infectious Diseases*, titled “Comparability of Gastrointestinal Microbiome and Bile Acid Profiles in Patients With First or Multiply Recurrent Clostridioides difficile Infection”, reported a post hoc analysis of the ECOSPOR IV Phase 3 trial, evaluating differences in gastrointestinal microbiome and bile acid profiles between patients experiencing a first recurrence C. difficile infection (frCDI) versus multiply recurrence infection (mrCDI). These data demonstrate that the underlying functional disease etiology is consistent in both first and multiply recurrent CDI patient populations, with VOWST demonstrating similar efficacy and drug pharmacology across the broad patient population.

We believe these data provide important clinical translation and further demonstrate the potential of live biotherapeutics to target specific microbiome functions that are linked to serious disease, including those that are not effectively treated with other drug modalities. The underlying data supporting these publications was developed using Seres' MbTx platform, which provides high-resolution assessment of drug pharmacology and functional mechanism of action. These data on bacterial function and pharmacology anchored the preclinical development of SER-155 and inform the continued development of Seres’ pipeline of next-generation live biotherapeutic products.

SER-155 for allo-HCT patients

We are developing SER-155, an investigational, oral, live biotherapeutic designed to decolonize GI pathogens, improve GI epithelial barrier integrity, and induce immune homeostasis to prevent bacterial BSIs, including those that can harbor AMR, as well as other pathogen associated negative clinical outcomes in patients undergoing allo-HCT. SER-155 is a live biotherapeutic candidate designed to prevent frequent, expensive, and fatal infections in blood cancer patients.

SER-155 contains 16 bacterial strains selected using our reverse translation discovery and development platform technologies to optimize SER-155’s functional profile. The design incorporates biomarker data from human clinical data and screening data from

nonclinical human cell-based assays and in vivo disease models. The bacteria consortia is designed to optimize: (i) the prevention of the growth of various *Enterococcaceae* and *Enterobacteriaceae* species known to potentially dominate the GI tract and lead to downstream negative clinical outcomes in medically compromised patients and that can harbor antibacterial resistance, (ii) the production of multiple bacterial metabolites that can promote mucosal and epithelial barrier integrity with the goal of reducing the likelihood of harmful bacteria translocating from the gut to the bloodstream through a compromised epithelium, and (iii) the production of multiple bacterial metabolites that can modulate immune pathways to induce immune tolerance with a potential impact on graft versus host disease, or GvHD.

The rationale for this program is based in part on published clinical evidence from our collaborators at Memorial Sloan Kettering Cancer Center showing that allo-HCT patients with decreased diversity of commensal microbes and pathogen domination in the gastrointestinal tract were significantly more likely to die due to infection and/or lethal GvHD (Peled et al., 2020). There are an estimated 40,000 allo-HCT procedures annually worldwide, and infection is one of the most common causes of mortality in these patients. The Center for International Blood & Marrow Transplant Research, or CIBMTR, reports that 19-28% of deaths in allo-HCT patients over 18 years of age within 100 days post-transplant are caused by infections and 5-14% by GvHD. In December 2023, we received Fast Track Designation for SER-155 to reduce the risk of infection and GvHD in allo-HCT patients. In December 2024, the FDA granted Breakthrough Therapy designation to SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HCT.

SER-155 Phase 1b Study (including placebo-controlled Cohort)

SER-155 has been evaluated in a Phase 1b study in patients undergoing allo-HCT. The SER-155 Phase 1b study included two cohorts. Cohort 1 was designed to assess safety and drug pharmacology, specifically the drug strain engraftment in the gastrointestinal tract. Cohort 1 included 13 subjects who received any dosing of the SER-155 regimen, with 11 subjects subsequently receiving an allo-HCT. Results from this cohort, announced in May 2023, showed SER-155 was generally well tolerated and resulted in successful drug strain engraftment and a reduction in pathogen domination in the GI microbiome relative to a historical control cohort.

Study Cohort 2 utilized a randomized, double-blinded 1:1 placebo-controlled design to further evaluate safety and drug strain engraftment, as well as key secondary and exploratory endpoints such as the incidence of bacterial bloodstream infections and related medical consequences such as febrile neutropenia and antibiotic use. Cohort 2 included 45 patients in the intention-to-treat (ITT) population. Of the ITT population, 20 received SER-155 and 14 received placebo, each of whom subsequently received an allo-HCT, with data available for clinical evaluation through day 100, the study's prespecified primary observation point. Exploratory hypothesis testing was conducted at the two-sided α=0.05 level. Ninety-five percent (95%) 2-sided confidence intervals (CIs) were determined, where specified. No adjustment for multiplicity was done. A subset of patient samples was available for drug pharmacology analysis.

The median age in Cohort 2 was 63, and most subjects had acute myeloid leukemia, acute lymphocytic leukemia, myelodysplastic syndrome or myeloproliferative neoplasia as their primary disease and received reduced-intensity conditioning pre-transplant. Most patients received peripheral blood stem cells from a matched unrelated donor. A majority received post-transplant cyclophosphamide as part of their graft-versus-host disease (GvHD) prophylaxis.

Results from Cohort 2, announced in September 2024, were consistent with the observations from Cohort 1. SER-155 was generally well tolerated, and no treatment-emergent serious adverse events related to drug were observed. SER-155 bacterial strains engrafted into the gastrointestinal tract of patients following the administration of SER-155.

The incidence of BSIs was significantly lower in the SER-155 arm compared with the placebo arm (2/20 (10%) vs. 6/14 (42.9%), respectively; [Odds Ratio: 0.15; 95% CI: 0.01, 1.13, p=0.0423]), which represents a relative risk reduction of approximately 77% and an absolute risk reduction of approximately 33%, resulting in a number needed to treat (NNT) of 3 for SER-155 to prevent a BSI event. In addition, while antibiotic starts were similar in each arm, patients administered SER-155 were treated with antibiotics for a significantly shorter duration compared to patients in the placebo arm (9.2 days vs. 21.1 days, respectively, with a mean difference of -11.9 days [95% CI: -23.85, -0.04; p=0.0494]). The incidence of febrile neutropenia was lower in patients administered SER-155 compared to placebo (65% vs. 78.6%, respectively; [Odds Ratio: 0.51; 95% CI: 0.07, 2.99; p=0.4674]). Six cases of gastrointestinal infections (C. difficile infections) were observed in the study, with four cases (20%) in the SER-155 arm and two cases (14.3%) in the placebo arm.

Recent changes in the allo-HCT standard of care and the increasing use of post-transplant cyclophosphamide as part of prophylactic therapy for GvHD have reduced rates of GvHD overall in this patient population. The rates of GvHD in the study were low, with two cases of grade 2 GvHD observed in each arm, and no cases of grade 3 or 4 GvHD were observed.

In Cohort 2, the ability to detect pathogen domination (i.e., relative abundance in the GI $\geq$30%) in the placebo arm, and differences between the study arms, was constrained due to the limited number of placebo stool samples (placebo patients submitted fewer stool samples) and an imbalance in the number of available stool samples between the arms. Observed pathogen domination events were low in the placebo and SER-155 arms with no significant differences identified. In a comparison of the prevalence of pathogen domination versus a larger allo-HCT historical control cohort, pathogen domination in SER-155 subjects was substantially lower, providing further evidence of SER-155 activity.

We believe the available study data from Cohort 1 suggest that SER-155 administration results in significantly lower incidence rates of gastrointestinal dominations with pathogens of clinical concern, such as *Enterococcaceae*, *Enterobacteriaceae*, *Streptococcaceae*, and *Staphylococcaceae*. We further believe the resulting Cohort 2 data, together with the Cohort 1 SER-155 Phase 1b study results provide encouraging evidence to support further development of SER-155 to potentially reduce GI associated bloodstream and AMR infections as well as increase immune tolerance in individuals undergoing allo-HCT for cancers and other serious conditions.

In October 2025, we presented new post hoc data from our SER-155 Phase 1b trial in an oral presentation at IDWeek in Atlanta, Georgia. The presentation included new post-hoc analysis from the completed SER-155 Phase 1b study describing differences between the SER-155 and placebo groups, including the bacterial and fungal organisms causing BSIs, BSI event clinical outcomes, antibacterial prophylaxis use, and patterns of AMR among the bacterial BSI organisms. These new data illustrated that BSIs occurred despite antibacterial prophylaxis, and that BSI bacteria exhibited AMR. Resistance to multiple antibacterial agent classes was observed only in the BSI bacteria from placebo-treated participants, two of whom had fatal outcomes related to their BSIs. These new data further support the potential of SER-155 as an innovative alternative approach to the significant unmet medical need for prevention of BSIs in HCT patients, especially those BSIs associated with AMR that increases the risk of morbidity and mortality.

In April 2026, we presented SER-155 Phase 1b study results, including biomarker and clinical pharmacology data, at the 2026 European Society of Clinical Microbiology and Infectious Diseases (ESCMID) global congress. Data showed that administration of SER-155 induced a significant and durable shift in GI microbiome composition relative to placebo, characterized by high relative abundance of SER-155 species. This shift is associated with improved GI epithelial barrier integrity that could reduce the likelihood of bacterial translocation from the GI to the bloodstream. These pharmacology results are consistent with the intended SER-155 mechanisms of action as well as the observation of significantly lower bloodstream infection incidence post allo-HCT in SER-155-administered participants.

In November 2026, we announced that results from our Phase 1b clinical study of SER-155 in adults undergoing allo-HCT were published in *Nature Medicine*, marking an important milestone for the program and providing recognition of the innovative science being advanced by the Company.

Exploratory biomarker data

In January 2025, we reported exploratory translational biomarker data from the SER-155 Phase 1b study which provided evidence supporting the intended therapeutic mechanisms, including promotion of intestinal epithelial barrier integrity to reduce the potential of bacterial translocation into the bloodstream, and reduction of systemic inflammatory responses. Results from this exploratory biomarker analysis showed that SER-155 was associated with lower levels of fecal albumin and lower concentrations of various plasma biomarkers associated with systemic inflammation (i.e., IFN-y, TNF-α, IL-17, and IL-8) in the HCT peri-transplant period, the period from the end of the first SER-155 treatment course through to neutrophil engraftment. The results support SER-155's intended mechanisms of action and reinforce the previously reported promising clinical study efficacy and safety data. These systemic inflammatory response observations further support the potential to develop our live biotherapeutics to address inflammatory and immune diseases, including ulcerative colitis and Crohn's disease.

In 2025, clinical and biomarker results from our biotherapeutic programs were presented at multiple leading industry meetings and conferences, including the 2025 Tandem Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and Center for International Blood and Marrow Transplant Research (CIBMTR), European Society for Blood and Marrow Transplantation (EBMT), Digestive Disease Week (DDW), and the 2025 American Society of Clinical Oncology (ASCO). We believe that exploratory biomarker data presented at recent medical meetings have supported the intended mechanisms of SER-155. We believe that the data generated suggest that live biotherapeutics could provide a novel treatment modality that could benefit patients living with gut-related inflammatory and immune diseases that are not effectively addressed today. Furthermore, research indicates that specific patient subpopulations optimally suited for biotherapeutic-based treatments may be identifiable.

Proposed SER-155 Phase 2 Study

The SER-155 Phase 2 study is expected to incorporate a well-powered, placebo-controlled design, which provides for a planned interim analysis to enable an expedited initial data readout. The SER-155 Phase 2 study is expected to enroll approximately 248 participants and incorporate an adaptive design and an interim data analysis when approximately half of the enrolled participants have reached the primary endpoint. We expect to obtain the interim clinical results within twelve months following study initiation, which we believe will facilitate timely engagement with the FDA on the design of a Phase 3 study and inform development in adjacent medically vulnerable patient populations. We believe that positive results, if achieved, from the Phase 2 study could enable advancement into a single Phase 3 trial to support registration.

Following advancement of key startup activities for the SER-155 Phase 2 study in allo-HCT, including the submission of a final protocol to the FDA in January 2026, study site evaluation and qualification with our CRO, and manufacturing of drug substance, we have paused additional investment in that program while continuing to seek funding for the Phase 2 study.

SER-428 - liquid formulation for ICU patients

In July 2025, we were awarded a grant from CARB-X to support the development of SER-428, an oral liquid formulation of an LBP based on SER-155 strains for medically vulnerable patient populations at risk of BSIs, including AMR infections, who cannot be dosed with oral capsules, such as intubated patients in the medical ICU. The CARB-X grant provides us with up to $3.6 million of funding for research, manufacture, and design of a Phase 1 clinical trial in ICU patients. SER-428 is designed to target the prevention of bloodstream infections in medical ICU patients by *Escherichia coli* and other gut-derived bacteria capable of harboring antibiotic resistance. Up to 50% of all preventable medical ICU deaths have been attributed to infections with *E. coli* and other gut-derived bacteria (Mayr, 2006). These infections are also the leading cost in the medical ICU (Neidell, 2012). When ICU patients with multidrug resistant, or MDR, infections survive hospitalization, they have high long-term morbidity with over 20% 30-day readmission rates (Chang, 2015; Mayr, 2017). Over 5 million patients are admitted to ICUs in the U.S. annually, and these admissions account for approximately 20% of all acute care hospitalizations (Barrett et al. 2024).

Infections with pathogenic, often MDR, bacteria are the leading cause of mortality in the medical ICU, causing up to 9 deaths for every 100 ICU patients admitted (Vincent, 2009). Most patients are admitted to the medical ICU with a known or suspected infection (i.e., sepsis) but, with targeted or empiric antibiotics, most recover from this initial infection. Once in the ICU, secondary, healthcare-associated infections frequently develop during the prolonged recovery from sepsis and are a significant driver of mortality. SER-428 is a novel approach that addresses both gut colonization and subsequent translocation by *E. coli* and other gut-derived pathogens to prevent a significant proportion of these secondary hospital acquired infections. SER-428 is in preclinical development, with IND-enabling activities ongoing and IND-readiness targeted by the end of 2026. We have advanced development and manufacturing of SER-428 and are designing a Phase 1b open label trial in collaboration with Columbia University to evaluate this therapeutic candidate in medical ICU patients at high risk of infection.

In October 2026, we presented preclinical data for SER-428 at IDWeek in Washington, D.C. in a poster presentation. In preclinical in vivo pathogen colonization models, oral administration of SER-428 led to up to a 1,000- fold reduction of Enterococcus faecium and Klebsiella pneumoniae. These findings support the potential of SER-428 to reduce GI pathogen abundance, bloodstream infections, and antimicrobial resistance in high-risk patients. The SER-428 liquid formulation was stable, including during the intended in-use period and following simulated feeding tube delivery.The findings presented provided important preclinical support for both the biological activity and the formulation characteristics of SER-428 as we continue to advance our clinical development plans for SER-428.

SER-147 for cirrhosis patients

We are also developing another proprietary live biotherapeutic composition, SER-147, designed to prevent bacterial bloodstream and spontaneous bacterial peritonitis, or SBP, infections in patients with metabolic disease, including chronic liver disease, or CLD. SER-147 was designed and optimized using our reverse translational therapeutics development platform. CLD is a progressive condition marked by deterioration of liver function and is reaching epidemic proportions affecting nearly 1.7 billion people worldwide, causing substantial health burden on afflicted countries (GBD 2017 Cirrhosis Collaborators, 2020, Clinical Liver Disease, 2021).

In the advanced stages of CLD, known as decompensated cirrhosis, patients exhibit significant immune dysfunction, microbiome disruption, and increased contact with the healthcare system, all of which drive increased susceptibility to bacterial infections such as SBP and BSIs (Bajaj et al., 2021, Albillos et al., 2022). Over 40% of patients with decompensated cirrhosis experience an infection within the first year of diagnosis. Antibiotics are the only prophylactic option for patients at high risk of infections like SBP, resulting in exposure to antibiotics for months or years. To combat increasing rates of AMR, antibacterial prophylaxis for primary SBP is no longer recommended for the majority of patients outside of those at very high-risk, leaving significant unmet need. Many cultivated live biotherapeutics currently in clinic are constrained by formulation technologies incompatible with concomitant medications commonly used in CLD.

SER-147 is in preclinical development. The program is ready to progress to IND-enabling activities, including manufacturing, in order to advance to clinical development, pending availability of funding.

Immunology and Inflammation

SER-603 for IBD patients

SER-603 is a novel, LBP candidate designed to improve response rates and durability of remission in patients with IBD, including ulcerative colitis, or UC, and Crohn's disease. SER-603 is optimized to address disruptions in the GI microbiome and to improve GI mucosal barrier integrity through the inhibition of inflammatory bacteria and associated metabolites, the promotion of epithelial barrier integrity to reduce the translocation of inflammatory molecules and barrier inflammation, and to induce immune homeostasis through non-immunosuppressive regulatory T cell, or T-reg, induction via T cell signaling. Our research on SER-603 has been primarily supported through a partnership with the Crohn’s and Colitis Foundation, or CCF. These efforts aim to (i) confirm the

functional phenotype and inflammatory state of patient subpopulations observed in our prior ulcerative colitis, or UC, clinical trials, and (ii) prioritize inflammatory targets and evaluate the potential to utilize biomarker-based patient selection and stratification for future studies.

Emerging clinical and preclinical evidence suggests that microbiome functional disruption contributes to disease activity in a defined subset of IBD patients. Observational and translational data from our prior SER-287 Phase 2b study and SER-301 Phase 1b study indicate that pharmacodynamic responses were greater in microbiome-defined subpopulations. These findings, along with external data demonstrating heterogeneity in microbiome-associated inflammatory responses, support the development of targeted, biomarker-informed live biotherapeutic strategies. We have discovered more than fifty GI bacterial features linked to inflammatory outcomes and have nominated and validated microbe associated biomarkers that can predict a response to current advanced therapies for IBD. Leveraging these biomarkers and our integrated preclinical and clinical data sets, SER-603 is optimized to address epithelial barrier dysfunction and microbiome-driven inflammation without systemic immunosuppression.

SER-603 is in preclinical development, with IND-enabling activities ongoing. SER-603 is being developed for use as a stand-alone therapy and/or as a mechanism-distinct adjunctive therapy in combination with biologics or small molecules. We continue to evaluate biomarker-based patient selection approaches and functional characterization strategies to inform future clinical development.

In April 2026, Dr. Ines Moura of the University of Leeds gave a presentation at the 2026 European Society of Clinical Microbiology and Infectious Diseases (ESCMID) global congress describing the use of an in vitro colonic model (MiGut) to recapitulate patient-specific microbiome composition and inflammatory responses in IBD. We are co-developing with Leeds models to evaluate drug strain engraftment in different patient microbiome backgrounds and measure resulting metabolic and immune functional responses. The collaboration with Leeds on MiGut enables the modeling of patient stratification, conditioning, and live biotherapeutic effects in a pharmacological model, to inform clinical development in IBD and broader opportunities in other diseases.

In May 2026, we presented data at the Digestive Disease Week, or DDW conference highlighting preclinical data supporting the design and potential of SER-603 in IBD. The poster, titled “The Rational Design of SER-603: A Next Generation Cultivated Microbial Consortia to Treat IBD,” which was selected as a DDW ‘Poster of Distinction,’ highlights our integrated approach to the design of microbiome therapeutics, combining rational strain selection and biomarker-driven patient stratification. SER-603 incorporates strains selected for engraftment and delivery of clinically relevant metabolites, including short-chain fatty acids, secondary bile acids, and tryptophan-derived molecules, with a therapeutic goal of inducing mucosal healing and regulating inflammatory pathways central to IBD pathophysiology, without immunosuppression. Its design integrates insights from human clinical datasets and reverse translational approaches to identify strains linked to key functional outputs, potentially enabling targeted modulation of inflammatory microbiome features, and is complemented by microbiome-based biomarkers associated with GI inflammation, to support patient stratification and to enrich for those patients most likely to benefit.

Intellectual Property

Patent Portfolio

We have an extensive patent portfolio directed to rationally designed ecologies of spores and microbes. The portfolio includes both company-owned patents and applications, and those that we have rights to as licensee. The patents and applications included in our portfolio cover both composition of matter and methods (e.g., method of treating). Our intellectual property rights related to SER-155, SER-147, SER-428 and/or SER-603 extend through at least part of 2046 (not including any potential term extension). We plan on continuing to broaden our patent portfolio. Currently, we have 21 active patent families, which includes 16 nationalized applications, three at the PCT stage, and one at the provisional stage. To date, we have obtained issuance of 33 U.S. patents (which includes three as licensee). Of the issued U.S. patents, 13 U.S. patents (including one as licensee) have been assigned to Nestlé Health Science as part of its purchase of VOWST.

In connection with the Transaction and pursuant to the Purchase Agreement, we transferred certain patents and trademarks affiliated with the VOWST Business to SPN at Closing. In addition, in connection with Closing, we entered into a cross-license agreement, or the Cross-License Agreement, with SPN. Under the Cross-License Agreement, we granted to SPN a perpetual, worldwide, non-exclusive, fully paid-up license under certain Seres patents that have been issued or will issue in the future and current know-how controlled by us that was not transferred to SPN pursuant to the Purchase Agreement. In the field of the treatment of CDI and recurrent CDI and associated complications, or collectively, the CDI Field, the license to SPN under such Seres patents and know-how is exclusive to SPN for five years after the Closing and co-exclusive between SPN and Seres following that five year period. The license from Seres to SPN is to issued Company patents that currently or in the future cover the Product or improvements thereof and know-how that is used or reasonably useful in connection with the exploitation of the VOWST Business. We also granted SPN an exclusive, perpetual, worldwide, fully paid-up license under issued Seres patents that currently or in the future cover the Product and improvements thereof and know-how that is used or reasonably useful in connection with the exploitation of the Product to exploit SER-262 in the CDI Field. SPN granted to us a perpetual, worldwide, non-exclusive license under the patents and know-how that are

transferred to SPN pursuant to the Purchase Agreement or developed under the TSA, for Seres' products for use outside of the CDI Field, and after five years from Closing for Seres products containing designed, cultivated, bacterial consortia not manufactured using human stool (excluding SER-262) in the CDI Field. From and after Closing, certain license agreements between us, SPN, and/or their respective affiliates terminated and are of no further force or effect, except as contemplated by the Purchase Agreement.

Regulatory Exclusivity

If we obtain marketing approval for any of our product candidates, we expect to receive reference product exclusivity against biosimilar products.

Financial Operations Overview

Revenue

To date we have not generated any revenues from the sale of products. Our revenues have been derived primarily from our agreements with our collaborators. See "–Liquidity and Capital Resources."

Operating Expenses

Our operating expenses since inception have consisted primarily of research and development activities and general and administrative costs. In connection with the TSA we entered into with NESA following the sale of the VOWST Business during the third quarter of 2024 through December 31, 2025, our operating expenses also consisted of certain passthrough costs incurred in performing duties under the TSA and manufacturing services related to the VOWST Business and operations.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates and other obligations, which include:

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations and other third parties that manufacture or test drug products for use in our preclinical and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel in our research and development functions;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the cost of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements;
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs; and
- labor and passthrough costs, reimbursable by Nestlé, incurred in performing duties under the TSA.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our unaudited condensed consolidated financial statements as prepaid or accrued research and development expenses.

Our primary focus of research and development since inception has been on our reverse translational platform and the subsequent development of our product candidates. Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to investigators, consultants, CROs in connection with our preclinical studies and clinical trials, lab supplies and consumables, and regulatory fees. We do not allocate employee-related costs and other indirect costs to specific research and development programs because these costs are deployed across multiple product programs under development.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We anticipate an overall decrease in research and development expenses in 2026 as compared to 2025, following the conclusion of the TSA, completion of the Phase 1b study of SER-155 in allo-HCT, and the cost reduction actions that were implemented in September 2025 and February 2026, including pausing investment in the SER-155 Phase 2 study and headcount reductions. Research and development expenses may increase in the future if and as we resume development of any clinical or preclinical programs. In 2025, research and development expenses included labor and passthrough costs, reimbursable by Nestlé, incurred in performing obligations under the TSA. Given the conclusion of the TSA as of December 31, 2025, these costs and related reimbursements are not expected to reoccur in 2026.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, commercial, business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses

for rent and maintenance of facilities, information technology costs and other operating costs. In 2025, general and administrative expenses also included labor and passthrough costs, reimbursable by Nestlé, incurred in performing duties under the TSA.

We expect that our general and administrative expenses will decrease in 2026 as compared to 2025, following the conclusion of the TSA as of December 31, 2025, reductions of our workforce and overall cost containment efforts. Over the longer term, general and administrative expenses may increase in the future as we continue to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing rules and the requirements of the SEC, director and officer insurance costs and investor and public relations costs.

Manufacturing Services

Under the TSA with NESA, beginning in the fourth quarter of 2024, we provided certain manufacturing services and related functions of the VOWST Business and operations. Expenses associated with the manufacturing services included certain facility-related, labor, lab supplies and consumables, and other manufacturing costs that would have been capitalized into inventory prior to the sale of VOWST Business.

We provided the manufacturing services until December 31, 2025. We do not expect to incur any expenses related to manufacturing services related to the VOWST business in the future, as the TSA and other Transaction-related obligations concluded on December 31, 2025.

Impairment of Long-Lived Assets

We recognized an impairment loss of $5.7 million and $11.5 million for the three and nine months ended September 30, 2026, respectively, related to our operating leases and the associated leasehold improvements as an indicator of impairment was deemed to exist and the carrying value of the asset group exceeded its fair value. Refer to Note 6, *Leases*, included elsewhere in this Quarterly Report on Form 10-Q, for more information.

Other Income (Expense), Net

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and investments.

Other Income (Expense), Net

Other income, net primarily consists of:

- sublease income;
- amortization of premiums or accretion of discounts on investments;
- gains and losses on foreign currency transactions;
- the amount Nestlé paid for costs associated with PRMS manufacturing; and reimbursement for certain labor and other passthrough costs of the transition services performed by the Company under the TSA; and
- gains or losses associated with the change in the Company's accrued liabilities due to SPN - related party.

Income Taxes

Since our inception in 2010, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. We did not provide for any income taxes in the three and nine months ended September 30, 2026 or 2025.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed consolidated financial statements requires the application of appropriate technical accounting rules and guidance, as well as the use of estimates. The application of these policies necessarily involves judgments regarding future events. These estimates and judgments, in and of themselves, could materially impact the condensed consolidated financial statements and disclosures based on varying assumptions. The accounting policies discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025, filed with the SEC on March 12, 2026, or the Annual Report, are considered by management to be the most important to an understanding of the consolidated financial statements because of their significance to the portrayal of our financial condition and results of operations. There have been no material changes to that information disclosed in our Annual Report during the three and nine months ended September 30, 2026.

Results of Operations

Comparison of Three Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the three months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		
	2026	2025	Change
Revenue:			
Grant revenue	593	351	242
Total revenue	593	351	242
Operating expenses:			
Research and development expenses	5,592	12,616	(7,024)
General and administrative expenses	5,448	9,476	(4,028)
Impairment of long-lived assets	5,705	—	5,705
Manufacturing services	—	736	(736)
Total operating expenses	16,745	22,828	(6,083)
Loss from operations	(16,152)	(22,477)	6,325
Other income (expense):			
Gain on sale of VOWST Business	—	27,222	(27,222)
Interest income	146	618	(472)
Other income (expense)	(280)	2,841	(3,121)
Total other income (expense), net	(134)	30,681	(30,815)
Net (loss) income	$ (16,286)	$ 8,204	$ (24,490)

Revenue

Total revenue was $0.6 million and $0.4 million for the three months ended September 30, 2026 and 2025 consisting of costs reimbursable under the CARB-X grant that we were awarded in the third quarter of 2025.

Research and Development Expenses

	Three Months Ended September 30,		
	2026	2025	Change
Live biotherapeutics platform	$ 2,297	$ 6,165	$ (3,868)
SER-155	282	1,220	(938)
Early stage programs	281	2	279
Total direct research and development expenses	2,860	7,387	(4,527)
Personnel-related (including stock-based compensation)	2,732	5,229	(2,497)
Total research and development expenses	$ 5,592	$ 12,616	$ (7,024)

Research and development expenses were $5.6 million for the three months ended September 30, 2026 and $12.6 million for the three months ended September 30, 2025. The decrease of $7.0 million was primarily due to the following:

- a decrease in personnel-related costs of $2.5 million primarily due to a decrease in salaries, bonuses, employee benefits expenses, and stock-based compensation expense due to lower headcount;
- a decrease of $3.9 million in expenses related to our live biotherapeutics platform and research and development operations primarily due to the conclusion of the TSA with Nestlé as of December 31, 2025, under which we incurred costs related to inventory shipments and storage of sample material that were reimbursed by Nestlé in 2025, as well as a reduction in facilities costs related to the Lease Amendment that was effective during the second quarter of 2026 and the Termination Agreement that was effective during the third quarter of 2026;
- a decrease of $0.9 million in expenses related to our SER-155 program as investment related to the Phase 2 study of SER-155 in allo-HCT was paused in February 2026; partially offset by
- an increase of $0.3 million in expenses related to our early stage programs primarily related to activities associated with the development of SER-428, for which the related reimbursements received from CARB-X are included within grant revenue.

General and Administrative Expenses

	Three Months Ended September 30,		
	2026	2025	Change
Personnel related (including stock-based compensation)	$ 1,964	$ 3,863	$ (1,899)
Professional fees	1,753	2,035	(282)
Facility-related and other	1,731	3,578	(1,847)
Total general and administrative expenses	$ 5,448	$ 9,476	$ (4,028)

General and administrative expenses were $5.4 million for the three months ended September 30, 2026 compared to $9.5 million for the three months ended September 30, 2025. The decrease of $4.0 million was primarily due to the following:

- a decrease in personnel-related costs of $1.9 million primarily due to a decrease in salaries, bonuses, employee benefits expenses, and stock-based compensation expenses due to lower headcount;
- a decrease in professional fees of $0.3 million due to lower legal fees, and
- a decrease in facility-related and other costs of $1.8 million primarily related to information technology costs that were incurred as part of the TSA and reimbursed by Nestlé that did not reoccur in 2026, as well as a reduction in facilities costs related to the Lease Amendment that was effective during the second quarter of 2026 and the Termination Agreement that was effective during the third quarter of 2026.

Manufacturing Services

Manufacturing services costs were incurred between the fourth quarter of 2024 and the end of 2025 as we performed PRMS manufacturing on behalf of Nestlé in accordance with the TSA. The expenses associated with manufacturing services included labor, materials, allocated facility-related, lab supplies and other manufacturing costs that would have been capitalized into inventory prior to the sale of VOWST Business. Following the conclusion of the TSA on December 31, 2025, no further manufacturing services costs were incurred and none are expected moving forward.

Impairment of Long-Lived Assets

Impairment of long-lived assets was $5.7 million for the three months ended September 30, 2026, consisting of $3.7 million related to right-of-use assets and $2.0 million related to the associated leasehold improvements. Refer to Note 6, *Leases*, included elsewhere in this Quarterly Report on Form 10-Q, for more information.

Other Income (Expense), Net

Other income (expense), net was $0.1 million of expense and $30.7 million of income for the three months ended September 30, 2026 and 2025, respectively. The decrease of $30.8 million in other income, net was due to the $27.2 million gain on sale of the VOWST business primarily due to the installment payment received from Nestlé in July 2025 that was conditioned on our material compliance with obligations under the TSA, as well as $2.0 million of reimbursement income associated with the performance of TSA services in the third quarter of 2025 that did not reoccur in 2026 due to the conclusion of the TSA at the end of 2025, a decrease in sublease income of $1.1 million, and a decrease in interest income of $0.4 million due to our lower cash balance.

Comparison of Nine Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the nine months ended September 30, 2026 and 2025:

	Nine Months Ended September 30,		
	2026	2025	Change
		(in thousands)	
Revenue:			
Grant revenue	1,687	351	1,336
Total revenue	1,687	351	1,336
Operating expenses:			
Research and development expenses	27,928	37,376	(9,448)
General and administrative expenses	20,579	31,617	(11,038)
Impairment of long-lived assets	11,512	—	11,512
Manufacturing services	—	5,952	(5,952)
Total operating expenses	60,019	74,945	(14,926)
Loss from operations	(58,332)	(74,594)	16,262
Other income (expense):			
Gain on sale of VOWST Business	25,000	79,588	(54,588)
Interest income	652	1,782	(1,130)
Other income (expense)	1,062	14,255	(13,193)
Total other income (expense), net	26,714	95,625	(68,911)
Net (loss) income	$ (31,618)	$ 21,031	$ (52,649)

Revenue

Total revenue was $1.7 million and $0.4 million for the nine months ended September 30, 2026 and 2025 consisting of costs reimbursable under the CARB-X grant. The increase reflects a full nine months of activity in 2026, compared with one quarter in 2025, as the award became effective in the third quarter of 2025.

Research and Development Expenses

	Nine Months Ended September 30,		
	2026	2025	Change
		(in thousands)	
Live biotherapeutics platform	$ 13,705	$ 17,096	$ (3,391)
SER-155	1,028	2,841	(1,813)
Early stage programs	863	8	855
Total direct research and development expenses	15,596	19,945	(4,349)
Personnel-related (including stock-based compensation)	12,332	17,431	(5,099)
Total research and development expenses	$ 27,928	$ 37,376	$ (9,448)

Research and development expenses were $27.9 million for the nine months ended September 30, 2026 and $37.4 million for the nine months ended September 30, 2025. The decrease of $9.4 million was primarily due to the following:

- a decrease in personnel-related costs of $5.1 million primarily due to a decrease in salaries, bonus, employee benefits expenses, and stock-based compensation expense due to lower headcount; and
- a decrease of $1.8 million in expenses related to our SER-155 program as investment related to preparation for the Phase 2 study of SER-155 in allo-HCT was paused in February 2026; and
- a decrease of $3.4 million in expenses related to our live biotherapeutics platform and research and development operations primarily due to a reduction in facilities costs related to the Lease Amendment that was effective during the second quarter of 2026 and the Termination Agreement that was effective during the third quarter of 2026, partially offset by an increase in facilities costs due to the conclusion of the TSA with Nestlé as of December 31, 2025, under which a portion of our facility costs and other operational costs were included within manufacturing services expenses and were reimbursed by Nestlé in 2025; partially offset by

- an increase of $0.9 million in expenses related to our early stage programs primarily related to activities associated with the development of SER-428, for which the related reimbursements received from CARB-X are included within grant revenue.

General and Administrative Expenses

	Nine Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 7,926	$ 11,761	$ (3,835)
Professional fees	4,909	7,370	(2,461)
Facility-related and other	7,744	12,486	(4,742)
Total general and administrative expenses	$ 20,579	$ 31,617	$ (11,038)

General and administrative expenses were $20.6 million for the nine months ended September 30, 2026 compared to $31.6 million for the nine months ended September 30, 2025. The decrease of $11.0 million was primarily due to the following:

- a decrease in personnel-related costs of $3.8 million primarily due to a decrease in salaries, bonus, employee benefits expenses, and stock-based compensation expenses due to the decrease in headcount period over period; and
- a decrease in professional fees of $2.5 million due to lower legal and consulting fees, and
- a decrease in facility-related and other costs of $4.7 million primarily related to information technology costs that were incurred as part of the TSA and reimbursed by Nestlé that did not reoccur in 2026 and facilities costs associated with the Termination Agreement that was effective during the third quarter of 2026.

Manufacturing Services

Manufacturing services costs were incurred between the fourth quarter of 2024 and the end of 2025 as we performed PRMS manufacturing on behalf of Nestlé in accordance with the TSA. The expenses associated with manufacturing services included labor, materials, allocated facility-related, lab supplies and other manufacturing costs that would have been capitalized into inventory prior to the sale of VOWST Business. Following the conclusion of the TSA on December 31, 2025, no further manufacturing services costs were incurred and none are expected moving forward.

Impairment of Long-Lived Assets

Impairment of long-lived assets was $11.5 million for the nine months ended September 30, 2026, consisting of $9.2 million related to right-of-use assets and $2.3 million related to the associated leasehold improvements. Refer to Note 6, *Leases*, included elsewhere in this Quarterly Report on Form 10-Q, for more information.

Other Income, Net

Other income (expense), net was $26.7 million of income and $95.6 million of income for the nine months ended September 30, 2026 and 2025, respectively. The decrease of $68.9 million in other income, net was due to the lower gain on sale of VOWST business in 2026 compared to 2025 of $54.6 million, as well as $11.8 million of reimbursement income associated with the performance of TSA services in the first half of 2025 that did not reoccur due to the conclusion of the TSA at the end of 2025, and a decrease in interest income of $1.1 million due to our lower cash balance. The $79.6 million gain on sale of the VOWST business recognized in the nine months ended September 30, 2025 was primarily due to the $75.0 million installment payments received from Nestlé in January and July 2025 that were conditioned on our material compliance with obligations under the TSA, while the $25.0 million gain on sale of VOWST business recognized in the nine months ended September 30, 2026 was related to the Milestone Termination Payment received from SPN in July and October 2026.

Liquidity and Capital Resources

Since our inception, we have generated revenue only from collaborations and have incurred recurring net losses from operations. We anticipate that we will continue to incur losses for at least the next several years. We will need additional capital to fund our operations, which include our research and development and general and administrative expenses, which we may obtain from additional financings, public offerings, research funding, additional collaborations, contract and grant revenue or other sources.

On August 5, 2024, we entered into the Purchase Agreement with SPN, pursuant to which we agreed to sell our VOWST Business, including inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of the Product to SPN and its designated affiliates, and SPN and its designated affiliates assumed certain liabilities from us. Our stockholders approved the Transaction at a special meeting of

stockholders held on September 26, 2024, and the Transaction closed on September 30, 2024. As consideration for the Transaction, SPN agreed to pay us:

(i) a cash payment, which was paid at Closing, of $100 million, less approximately $17.9 million owed by us to an affiliate of SPN as of March 31, 2024 under the prior license agreement between us and the SPN affiliate, less approximately CHF 2.0 million in satisfaction of fees due under an existing manufacturing agreement between us and Bacthera;

(ii) cash installment payments of $50 million, which was received on January 15, 2025, and $25 million, which was received on July 1, 2025 (offset by $1.4 million paid by us to Nestlé on July 1, 2025 related to certain employment obligations assumed by SPN, as described below), conditioned on our material compliance with obligations under the TSA entered into at Closing between us and NESA;

(iii) prepayment of the $60 million Prepaid Milestone, which was paid in cash at Closing; and

(iv) potential future sales milestone payments of $125.0 million and $150.0 million, tied to the achievement of worldwide annual net sales of the Product of $400.0 million and $750.0 million, respectively, during the Milestone Period.

As a condition to Closing, we and SPN entered into the Securities Purchase Agreement, pursuant to which SPN purchased 714,285 shares of Common Stock at Closing, at a purchase price per share of $21.00, for an aggregate purchase price of $15.0 million.

On June 2, 2026, we entered into Amendment No. 1 (the “APA Amendment”) to the Purchase Agreement. Pursuant to the APA Amendment, the parties agreed to terminate SPN’s obligations with respect to the Milestone Payments described in clause (iv) above and eliminate the milestone interest payments that would have been due from us to SPN. In consideration for the foregoing, SPN agreed to a one-time payment to us of $25.0 million (the "Milestone Termination Payment"), payable in two equal installments of $12.5 million, with the first installment paid on July 1, 2026 and the second installment paid on October 1, 2026. As a result, no further milestone payments are payable to us under the Purchase Agreement.

In May 2021, we entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, to sell shares of our common stock, with aggregate gross sales proceeds of up to $150.0 million, from time to time, through an “at the market” equity offering program under which Cowen acts as sales agent. During the three and nine months ended September 30, 2026, we sold 113,643 and 371,725 shares of common stock under the Sales Agreement, at an average price of approximately $7.45 and $8.37 per share, raising aggregate net proceeds of approximately $0.7 million and $2.9 million after deducting an aggregate commission of approximately 3%. During the nine months ended September 30, 2025, we sold 54,806 shares of common stock under the Sales Agreement, at an average price of approximately $18.60 per share, raising aggregate net proceeds of approximately $1.0 million after deducting an aggregate commission of approximately 3% and other issuance costs. As of September 30, 2026, we have sold 2,560,420 shares of common stock under the Sales Agreement, at an average price of approximately $25.33 per share, raising aggregate net proceeds of approximately $62.2 million after deducting an aggregate commission of approximately 3% and other issuance costs. On August 13, 2026, we entered into a Sales Agreement, or the 2026 Sales Agreement, with TD Securities (USA) LLC, or TD Cowen, to sell shares of our common stock, with aggregate gross sales proceeds of up to $100.0 million, from time to time, through an "at the market" equity offering program under which TD Cowen acts as sales agent. During the three months ended September 30, 2026, no shares were sold under the 2026 Sales Agreement.

As of September 30, 2026, we had cash and cash equivalents totaling $17.5 million and an accumulated deficit of $1,004.0 million. For the nine months ended September 30, 2026, we incurred a loss from operations of $58.3 million. We expect that our operating losses and negative cash flows will continue for the foreseeable future.

Under applicable accounting standards, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within 12 months after the date the consolidated financial statements are issued. The ability to obtain sufficient proceeds from additional equity offerings, collaborations or other financing with terms favorable or acceptable to us cannot be considered probable, as these events are outside of our control. Based on our currently available cash resources, the $12.5 million Milestone Termination Payment received from SPN in October 2026, and considering our future operating plans, we anticipate that we will require additional funding following the first quarter of 2027. Accordingly, management has concluded that these circumstances raise substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. We will need to generate significant revenues to achieve profitability, and we may never do so. Because of the numerous risks and uncertainties associated with the development of our current and any future product candidates, the development of our platform and technology and because the extent to which we may enter into collaborations with third parties for development of any of our product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses required for completing the research and development of our product candidates.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Nine Months Ended September 30,	
	2026	2025
	(in thousands)	
Cash (used in) provided by operating activities	$ (49,231)	$ 15,827
Cash provided by (used in) investing activities	12,566	(223)
Cash provided by financing activities	2,895	1,241
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (33,770)	$ 16,845

Operating Activities

During the nine months ended September 30, 2026, cash used in operating activities was $49.2 million due to a net loss of $31.6 million and changes in our operating assets and liabilities of $16.9 million and non-cash charges of $0.7 million. Non-cash charges consisted of the impairment loss of $11.5 million, gain related to the APA Amendment of $25.0 million, stock-based compensation expense of $5.4 million, $5.1 million related to the amortization of right-of-use assets, $1.9 million of depreciation and amortization, and $0.4 million loss on disposal of fixed assets. Changes in our operating assets and liabilities during the nine months ended September 30, 2026 consisted of a decrease in operating lease liabilities of $16.3 million, a decrease in accounts payable of $0.2 million, a decrease in accrued expenses and other current and long-term liabilities of $2.0 million, partially offset by a decrease in prepaid expenses and other current and other non-current assets of $1.2 million and a decrease in accounts receivable due from SPN of $0.4 million.

During the nine months ended September 30, 2025, cash provided by operating activities was $15.8 million due to net income of $21.0 million and non-cash charges of $17.1 million, partially offset by changes in our operating assets and liabilities of $22.3 million. Non-cash charges consisted of stock-based compensation expense of $7.6 million, $6.2 million related to the amortization of right-of-use assets, and $3.2 million of depreciation and amortization. Changes in our operating assets and liabilities during the nine months ended September 30, 2025 consisted of a decrease in accrued liabilities due to SPN of $13.3 million, a decrease in operating lease liabilities of $6.4 million, a decrease in accrued expenses and other current and long-term liabilities of $4.2 million, a decrease in accounts payable of $2.4 million, and an increase in accounts receivable relating to the CARB-X program of $0.4 million, partially offset by a decrease in prepaid expenses and other current and other non-current assets of $2.7 million, and a decrease in accounts receivable due from SPN of $1.6 million.

Investing Activities

During the nine months ended September 30, 2026, net cash provided by investing activities was $12.6 million, primarily consisting of $12.5 million received from SPN related to the APA Amendment.

During the nine months ended September 30, 2025, net cash used in investing activities was $0.2 million, consisting entirely of purchases of property and equipment.

Financing Activities

During the nine months ended September 30, 2026, net cash provided by financing activities was $2.9 million, consisting of $2.9 million from the issuance of common stock under our at the market equity program, net of issuance costs and less than $0.1 million from the issuance of common stock under our 2015 Employee Stock Purchase Plan, or ESPP.

During the nine months ended September 30, 2025, net cash provided by financing activities was $1.2 million, consisting of $1.0 million from the issuance of common stock under our at the market equity program, net of issuance costs and $0.2 million from the issuance of common stock under our 2015 ESPP.

Funding Requirements

Our expenses may increase in connection with our ongoing clinical development activities and research and development activities. In addition, we expect to continue to incur additional costs associated with operating as a public company. We anticipate that our future expenses will increase if and as we:

- invest in our early-stage pipeline product candidates, including SER-603 in IBD and SER-155 in irEC;
- conduct clinical trials for SER-155 in allo-HCT, irEC, and other medically vulnerable populations, including potentially SER-428 in ICU patients;
- make strategic investments in manufacturing capabilities;

- maintain and augment our extensive proprietary live biotherapeutic drug development know-how that may be used to support future research and development efforts, including our intellectual property portfolio and intellectual property that we may opportunistically acquire;
- establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any other products for which we may obtain regulatory approval;
- perform our obligations under any agreements with collaborators;
- seek to obtain regulatory approvals for our product candidates; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

Because of the numerous risks and uncertainties associated with the development of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- the cost of conducting clinical trials for SER-155 in allo-HCT, irEC, and other targeted indications, and other product candidates in our pipeline;
- the cost of manufacturing our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and research activities;
- the costs, timing and revenue, if any, of potential future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for our current or future product candidates and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Additionally, part of our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. Additionally, market volatility resulting from macroeconomic conditions, or other factors could also adversely impact our ability to access capital as and when needed. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as common stockholders. Any debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Additional debt or preferred equity financing may also require the issuance of warrants, which could potentially dilute our stockholders' ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, in addition to our existing collaboration agreements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity, debt financings, or collaborations when needed, we may be required to delay, limit, reduce or terminate our product development programs or any potential future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

As discussed in Note 1 of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within 12 months after the date the condensed consolidated financial statements are issued. The ability to obtain sufficient proceeds from additional equity offerings, collaborations or other financing with terms favorable or

acceptable to us cannot be considered probable, as these events are outside of our control. Accordingly, management has concluded that these circumstances raise substantial doubt about our ability to continue as a going concern. Based on our currently available cash resources and the $12.5 million Milestone Termination Payment received from SPN in October 2026, and considering our future operating plans, we anticipate that we will require additional funding following the first quarter of 2027.

Contractual Obligations and Commitments

The disclosure of our contractual obligations and commitments was included in our Annual Report. Except for the Lease Amendment and the Termination Agreement described in Note 6, *Leases,* to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q there have been no material changes from the contractual commitments and obligations previously disclosed in our Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk from changes in interest rates and inflation. These market risks arise in the normal course of business. As of September 30, 2026, there have been no material changes to the information included under Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in our Annual Report on Form 10-K for the year ended December 31, 2025.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Quarterly Report. Based on such evaluation, our principal executive officer and principal financial officer concluded that as of September 30, 2026, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors

Our business faces significant risks and uncertainties. Accordingly, in evaluating our business, you should carefully consider the risk factors discussed below, as well as the other information included or incorporated by reference in this Quarterly Report, including our condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below or elsewhere in this report could harm our business, financial condition, results of operations or growth prospects.

Risks Related to Our Financial Position and Need for Additional Capital

We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.

Based on our currently available cash resources and the $12.5 million Milestone Termination Payment received from SPN in October 2026, and considering our future operating plans, we anticipate that we will require additional funding following the first quarter of 2027. The ability to obtain additional equity or other financing, including through partnerships, with terms favorable or acceptable to us cannot be considered probable according to the applicable accounting standards because they are outside our control. Therefore, there is substantial doubt about our ability to continue as a going concern for at least 12 months from the date that our condensed consolidated financial statements for the nine months ended September 30, 2026 were issued. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing or enter into a partnership. If potential collaborators or partners decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. We have prepared our consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q do not include any adjustments to reflect the possible inability of the Company to continue as a going concern within 12 months after the issuance of such financial statements.

We will need additional funding in order to advance development of our product candidates (including to conduct the Phase 2 study of SER-155 in allo-HCT and to advance our earlier stage programs) and commercialize our product candidates, if approved. If we are unable to raise capital or secure a partnership or other business development transaction, we could be required to implement further cost-reduction measures, reduce or delay our product development programs or any potential future commercialization efforts, or pursue other alternatives which could include seeking relief under the U.S. Bankruptcy Code or winding down our operations.

Our expenses may increase in connection with our ongoing activities, particularly if we further SER-155 clinical studies, and research, develop and initiate clinical trials of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur costs related to product manufacturing and commercialization, including marketing, sales and distribution, and may not generate meaningful product revenues or collaboration profit in the near future. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital or secure a partnership when needed or on attractive terms, we could be forced to reduce or delay our product development programs or potential future commercialization efforts, or pursue other alternatives, which could include seeking relief under the U.S. Bankruptcy Code or winding down our operations.

We are actively seeking a business development transaction, which may include a partnership, to provide financial support and share in our vision to realize the clinical and commercial value of SER-155. Our strategic discussions are focused on supporting SER-155 clinical advancement to reduce the risk of bloodstream infections, including life-threatening and AMR infections, in medically vulnerable patient populations. We believe that SER-155 and other cultivated live biotherapeutic candidates could be developed in additional patient populations beyond allo-HCT, including autologous-HCT patients, cancer patients with neutropenia, CAR-T recipients, individuals with chronic liver disease, solid organ transplant recipients, as well as patients in the intensive care unit and long-term acute care facilities. We are also exploring collaborations to advance the development of our investigational biotherapeutics in inflammatory and immune diseases, including ulcerative colitis and Crohn's disease.

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. Our future capital requirements will depend on many factors, including:

- the cost of developing our pipeline product candidates, including SER-603 in IBD and SER-155 in irEC;
- the cost of conducting clinical trials for SER-155 in allo-HCT, irEC, and other targeted indications, and other product candidates in our pipeline;
- the cost of manufacturing our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and research activities;
- the costs, timing and revenue, if any, of potential future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Additionally, market volatility resulting from current macroeconomic conditions, such as the conflicts involving Ukraine and Russia and Israel and its surrounding regions, trade wars or related uncertainty between the U.S. and other nations, including China, or other governmental action related to tariffs or international trade agreements or policies, and related impacts, or other factors could also adversely impact our ability to access capital as and when needed. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders and may decrease our stock price. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay, or discontinue one or more of our research or development programs or any product candidates, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially adversely affect our business, financial condition and results of operations. We may pursue strategic partnerships or collaborations or other alternatives with one or more parties. We can provide no assurance that we will be successful in securing any strategic partnership, collaboration, or alternative, or that any such partnership, collaboration or alternative that we secure will achieve its intended benefits or have a positive impact on our financial condition or business.

We are a clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. As of September 30, 2026, we had cash and cash equivalents totaling $17.5 million and an accumulated deficit of $1,004.0 million. For the nine months ended September 30, 2026, we incurred a net loss from operations of $58.3 million. As noted elsewhere in this Quarterly Report on Form 10-Q, we have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. To date, we have financed our operations through the public offerings of our common stock, private placements of our common stock and preferred stock, payments under our prior collaboration agreements and loan facility, and payments from government entities for research grants. We have devoted substantially all of our financial resources and efforts to developing our live biotherapeutics platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We have only developed one FDA-approved product, VOWST, which was sold to SPN in September 2024. We have not completed development of any of our other product candidates, which we call live biotherapeutic candidates, or other drugs or biologics. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our expenses may increase substantially in connection with our ongoing and future activities, particularly if and as we:

- invest in our early-stage pipeline product candidates, including SER-603 in IBD and SER-155 in irEC;
- conduct clinical trials for SER-155 in allo-HCT, irEC, and for other medically vulnerable populations;
- advance research and development activities supported by partnerships;
- make strategic investments in manufacturing capabilities;
- maintain and augment our extensive proprietary live biotherapeutic drug development know-how that may be used to support future research and development efforts, including our intellectual property portfolio and intellectual property that we may opportunistically acquire;
- establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we have obtained and in the future may obtain regulatory approval;
- perform our obligations under any agreements with collaborators;
- seek to obtain regulatory approvals for our product candidates; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

To become and remain profitable, we must succeed in developing and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we have already obtained and may in the future obtain regulatory approval. We are in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, secure a partnership, expand our business, maintain our research and development and any potential future commercialization efforts, diversify our product offerings or even continue our operations.

Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

Since our inception in October 2010, we have devoted substantially all of our resources to developing our clinical and preclinical program, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. Other than with respect to VOWST, which was sold to SPN in September 2024, we have not yet demonstrated our ability to obtain regulatory approvals, and we have limited experience in demonstrating our ability to manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We may not be able to realize the anticipated benefits of the Transaction, and we may face new challenges as a smaller, less diversified company.

We may not be able to realize the anticipated benefits from the Transaction, including deploying the proceeds from the Transaction to advance SER-155 and support our pipeline of wholly-owned cultivated live biotherapeutic candidates. Our ability to realize the anticipated benefits of the Transaction and the success of the remaining company is subject to various risks and uncertainties, including the possibility that we may not be able to successfully use our live biotherapeutics platform to build a pipeline of product candidates and develop additional marketable drugs, and the possibility that we will not be able to obtain, or experience delays in obtaining, required regulatory approvals.

The Transaction resulted in the Company being a smaller, less diversified company with a more limited remaining business concentrated on SER-155, which recently completed a Phase 1b study in patients undergoing allogeneic hematopoietic stem cell transplantation, and our other wholly-owned cultivated live biotherapeutic candidates. As a result, we may be more susceptible to changing market conditions, including fluctuations and risks particular to preclinical and clinical-stage companies, than a more diversified company, which could adversely affect our remaining business, financial condition and results of operations. In addition, the diversification of our costs and cash flows diminished following the Transaction, such that our results of operations, cash flows, working capital and financing requirements may be subject to increased volatility and our ability to fund capital expenditures and investments or satisfy other financial commitments may be diminished.

We will need to secure additional funding to maintain operations beyond our current cash runway. Based on our currently available cash resources, the $12.5 million Milestone Termination Payment received from SPN in October 2026, and considering our future operating plans, we anticipate that we will require additional funding following the first quarter of 2027. However, due to our smaller business size and the early stage of development of our remaining assets, there can be no assurance that we will be able to raise the required capital on favorable terms, or at all. This potential inability to obtain necessary funding could have a material adverse effect on our growth prospects, financial condition, and results of operations.

We may also face new challenges with maintaining employee morale and retaining key management and other employees and retaining existing business and operational relationships, including with third parties, employees and other counterparties that otherwise prefer to transact with larger companies (or will only transact with smaller companies on less favorable terms).

Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates

We are early in our development efforts of our product candidates and may not be successful in our efforts to use our reverse translational platform to build a pipeline of product candidates and develop additional marketable drugs.

We are using our reverse translational platform to develop live biotherapeutic candidates. We are at an early stage of development of our product candidates and our platform may never lead to approvable or marketable drugs. We are developing product candidates that are designed to reduce infection and treat diseases where the microbiome is implicated. We may have problems applying our technologies to these areas, and our product candidates may not be effective in reducing infection and disease. Our product candidates may not be suitable for clinical development, including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and, if approved, achieve market acceptance.

The success of our product candidates will depend on several factors, including the following:

- completion of preclinical studies and clinical trials with positive results;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing our own, commercial manufacturing capabilities;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- entering into new collaborations throughout the development process as appropriate, from preclinical studies through to commercialization;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidates, if approved;
- protecting our rights in our intellectual property portfolio;

- operating without infringing or violating the valid and enforceable patents or other intellectual property of third parties;
- maintaining a continued acceptable safety profile of our product candidates, if approved, following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our product candidates and technology.

If we or our collaborators do not successfully develop and commercialize our product candidates we will not be able to obtain product revenue or collaboration profit in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

Our product candidates are based on live biotherapeutics, which is a novel approach to therapeutic intervention.

Our product candidates are based on live biotherapeutics, a novel class of biological drugs, which are designed to treat disease by modulating the microbiome to restore health by repairing the function of a disrupted microbiome to a non-disease state. To our knowledge, VOWST is the first oral product based on this approach to receive FDA approval. We cannot be certain that our approach will lead to the development of additional approvable or marketable products or that we will be able to manufacture at commercial scale. Finally, the FDA or other regulatory authorities may lack experience in evaluating the safety and efficacy of novel product candidates based on live biotherapeutics, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent any potential future commercialization of our product candidates.

Clinical drug development involves a risky, lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and potential future commercialization of our product candidates.

It is difficult to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing, and our clinical trials may not be successful. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim or preliminary results of a clinical trial, that we may from time to time announce, do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks.

In addition, we cannot be certain as to what type and how many clinical trials the FDA, or other regulatory authorities, will require us to conduct before we may successfully gain approval to market any of our product candidates. Prior to approving a new therapeutic product, the FDA (or other regulatory authorities) generally requires that safety and efficacy, or with respect to biological products such as our live biotherapeutic candidates, safety, purity and potency, be demonstrated in two adequate and well-controlled clinical trials. In some situations, evidence from a Phase 2 trial and a Phase 3 trial or from a single Phase 3 trial can be sufficient for FDA approval, such as in cases where the trial or trials provide highly reliable and statistically strong evidence of an important clinical benefit.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- regulatory authorities or institutional review boards or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- failures or delays in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may demonstrate undesirable side effects or produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulatory authorities or institutional review boards or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulatory authorities may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- regarding trials managed by any current or future collaborators, our collaborators may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but potentially suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- lose the support of current or any future collaborators, requiring us to bear more of the burden of development of certain compounds;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as we intend or desire;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be subject to increased pricing pressure; or
- have the product removed from the market after obtaining marketing approval.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. These authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators, IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Additional clinical trials or changes in our development plans could cause us to incur significant development costs, delay or prevent the potential future commercialization of our product candidates or otherwise adversely affect our business.

In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted with respect to clinical trials. For instance, the regulatory landscape related to clinical trials in the European Union, or EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as contract research organizations, or CROs, may impact our development plans.

The UK regulatory framework in relation to clinical trials is derived from the now-repealed EU Clinical Trials Directive (as implemented into UK law, through the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended). In April 2025, the UK government adopted the Medicines for Human Use (Clinical Trials) Amendment Regulations. The amendment, which took full effect in April 2026, aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our business may be impacted.

Delays or difficulties in the enrollment of patients in clinical trials could result in our receipt of necessary regulatory approvals being delayed or prevented.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. These trials and other trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal or adverse events. These types of developments could cause us to delay the trial or halt further development.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, there may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study.

Patient enrollment is also affected by other factors including:

- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the availability of other treatments for the disease under investigation;
- the existence of competing clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- our payments for conducting clinical trials;
- the patient referral practices of physicians;

- the burden, or perceived burden, of the clinical study;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials or a delayed rate of enrollment would result in significant delays and could require us to abandon one or more clinical trials altogether.

Interim "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

Interim, top-line or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or any collaborators will not be able to commercialize our product candidates or will not be able to do so as soon as anticipated, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and potential future commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate in any jurisdiction will prevent us and any collaborators from commercializing the product candidate in that jurisdiction and may affect our plans for potential future commercialization in other jurisdictions as well. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy, or with respect to biologics such as our live biotherapeutic candidates, safety, purity and potency. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, risky and may take many years. The scope and amount of clinical data required to obtain marketing approvals can vary substantially from jurisdiction to jurisdiction, and it may be difficult to predict whether a particular regulatory body will require additional or different studies than those conducted by a sponsor, especially for novel product candidates such as our live biotherapeutic candidates. The FDA or foreign regulatory authorities may delay, limit, or deny approval to market our product candidates for many reasons, including: our inability to demonstrate that the clinical benefits of our product candidates outweigh any safety or other perceived risks; the regulatory authority's disagreement with the interpretation of data from nonclinical or clinical studies; the regulatory authority's requirement that we conduct additional preclinical studies and clinical trials; changes in marketing approval policies during the development period; changes in or the enactment of additional statutes or regulations, or changes in regulatory review process for each submitted product application; or the regulatory authority's failure to approve the manufacturing processes or third-party manufacturers with which we contract. For instance, the EU pharmaceutical legislation has been undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published on April 26, 2023. The proposed changes were since discussed and negotiated by the European Parliament and the Council of the EU as part of the EU ordinary legislative process. A provisional agreement has been reached by the European Parliament and Council of the EU on the proposed revisions on December 11, 2025. The proposed revisions (affecting the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc.) remain to be formally adopted by the two institutions, which is not anticipated before early 2026. The proposed changes are not expected to enter into application before 2028 and may however have a significant impact on the biopharmaceutical industry in the long term.

Additionally, regulatory authorities have substantial discretion in the approval process and may refuse to accept or file a marketing application if deficient. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

Furthermore, our product candidates may not receive marketing approval even if they achieve their specified endpoints in clinical trials. Clinical data are often susceptible to varying interpretations and many companies that have believed that their products performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory authority approval for their products. The FDA or foreign regulatory authorities may disagree with our trial design and our interpretation of data from nonclinical and clinical studies, or they may require additional confirmatory or safety evidence beyond our existing clinical studies. Upon the FDA's review of data from any pivotal trial, it may request that the sponsor conduct additional analyses of the data or gather more data and, if it believes the data are not satisfactory, could advise the sponsor to delay submitting a marketing application.

Even if we eventually complete clinical testing and receive approval of a biologics license application, or BLA, or foreign marketing authorization for one of our product candidates, the FDA or the applicable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, which may be required after approval. The FDA or the applicable foreign regulatory authority may also approve our product candidates for a more limited indication and/or a narrower patient population than we originally request, and the FDA, or applicable foreign regulatory authority, may not approve the labeling that we believe is necessary or desirable for the successful potential future commercialization of our product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent potential commercialization of our product candidates and would materially adversely impact our business and prospects.

The development of therapeutic products targeting the underlying biology of the human microbiome is an emerging field, and it is possible that the FDA and other regulatory authorities could issue regulations or new policies in the future that could adversely affect our live biotherapeutic candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

A Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We have and may in the future seek Fast Track designation for some of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug or biologic sponsor may apply for Fast Track designation. We received Fast Track designation for SER-155 to reduce the risk of infection and GvHD in patients undergoing allo-HCT. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. Once granted, Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, and a BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the

submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

The FDA has broad discretion whether or not to grant this designation, and even if we believe another particular product candidate is eligible for this designation, we cannot be certain that the FDA would decide to grant it. Even with Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Fast Track designation does not assure ultimate approval by the FDA. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

A Breakthrough Therapy, or other similar designations by the FDA for our product candidates may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

In December 2024, we received Breakthrough Therapy designation for SER-155 for the reduction of BSIs in patients 18 years and older undergoing allo-HCT. We may seek these or other designations for future product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed in early clinical development. For drugs or biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Drugs designated as breakthrough therapies by the FDA also receive all of the Fast Track program features, including eligibility for rolling review of the associated marketing application.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. The receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, not all products designated as breakthrough therapies ultimately will be shown to have the substantial improvement over available therapies suggested by the preliminary clinical evidence at the time of designation. As a result, if a Breakthrough Therapy designation for any future designation we receive is no longer supported by subsequent data, the FDA may rescind the designation.

We may seek PRIME designation by EMA or other designations, schemes or tools in the EU for one or more of our product candidates, which we may not receive. Such designations may not lead to a faster development or regulatory review or approval process and do not increase the likelihood that our product candidates will receive marketing authorization.

We may seek EMA PRIME (PRIority MEdicines) designation or other designations, schemes or tools for one or more of our product candidates. In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the Breakthrough Therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the European Medicines Agency's, or EMA, support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The benefits of a PRIME designation include the appointment of a rapporteur before submission of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Even if we believe one of our product candidates is eligible for PRIME, the EMA may disagree and instead determine not to make such designation. The EMA PRIME scheme or other schemes, designations, or tools, even if obtained or used for any of our product candidates may not lead to a faster development, regulatory review or approval process compared to therapies considered for approval under conventional procedures and do not assure ultimate approval. In addition, even if one or more of our product candidates is eligible to the PRIME scheme, the EMA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened.

Product developers that benefit from PRIME designation may be eligible for accelerated assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this is not guaranteed.

The competent regulatory authorities in the EU have broad discretion whether to grant such an accelerated assessment, and, even if such assessment is granted, we may not experience a faster development process, review or authorization compared to conventional procedures. Moreover, the removal or threat of removal of such an accelerated assessment may create uncertainty or delay in the clinical development of our product candidates and threaten the commercialization prospects of our product candidates, if approved. Such an occurrence could materially impact our business, financial condition and results of operations.

We may seek orphan drug designation for some of our product candidates but may not be able to obtain it.

We may seek orphan drug designation for some of our future product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. In the United States, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a product with an orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or other regulatory authorities from approving another marketing application for the same drug and same disease or condition during that time period, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. The applicable period is seven years in the United States and ten years in the EU. The European exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that a product no longer meets the criteria for orphan designation, if the product is sufficiently profitable so that market exclusivity is no longer justified, or the prevalence of the condition has increased above the orphan designation threshold. Orphan drug exclusivity may be lost if the FDA or other regulatory authorities determine that the request for designation was materially defective or if the manufacturer is unable to assure a sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective.

Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity for a product may not effectively protect the product from competition because different drugs and biologics can be approved for the same disease or condition. Even after an orphan drug or biologic is approved, the FDA or other regulatory authorities can subsequently approve the same drug or biologic for the same disease or condition if the FDA or other regulatory authorities conclude that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time nor gives the drug any advantage in the regulatory review or approval process.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, or policy changes could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA’s and other regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA’s and other regulatory authorities' ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other regulatory authorities, such as the EMA, may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary regulatory authorities, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, which have led to substantial changes in senior personnel, and it remains unclear the degree to which these efforts and the resulting personnel changes may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if funding shortages, staffing limitations, or changes in administrative policy delay or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. It could also impact our ability to access the public markets and obtain necessary capital in order to fund our operations.

Risks Related to our Dependence on Third Parties and Manufacturing

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials.

Our reliance on these third parties for research and development activities will reduce our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety and welfare of trial participants are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations or similar regulatory requirements outside the United States. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or data privacy and security laws. Other countries' regulatory authorities also have requirements for clinical trials with which we must comply. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, *ClinicalTrials.gov*, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed, or terminated or may need to be repeated. If any of the foregoing occur, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or potential commercialization of our products, if and when approved, producing additional losses and depriving us of potential product revenue.

We rely on third parties for certain aspects of the manufacture of our product candidates, and we expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or that such quantities may not be available at an acceptable cost, which could delay, prevent or impair our development or potential future commercialization efforts.

We rely, and expect to continue to rely, on third parties for certain aspects of materials supply for our product candidates in preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates on a timely basis or at all, or that such quantities will be available at an acceptable cost or quality, which could delay, prevent or impair our development or potential future commercialization efforts.

We rely on third-party manufacturers, which entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- failure of third-party manufacturers to perform the manufacturing process adequately;
- breach of supply agreements by the third-party manufacturers;
- failure to supply components, intermediates, services, or product according to our specifications;

- failure to supply components, intermediates, services, or product according to our schedule or at all;
- misappropriation or disclosure of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of agreements by third-party manufacturers at times that are costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current good manufacturing processes, or cGMP, regulations or similar regulatory requirements inside or outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products, if and when approved. If our manufacturers are unable to comply with cGMP regulation or similar regulatory requirements outside the United States or if the FDA or other regulatory authorities do not approve their facility upon a pre-approval inspection, our therapeutic candidates may not be approved or may be delayed in obtaining approval. In addition, there are a limited number of manufacturers that operate under cGMP regulations and similar regulatory requirements outside the United States that might be capable of manufacturing our products, if and when approved. Therefore, our product candidates and any future products that we may develop may compete with other products for access to manufacturing facilities. Any failure to gain access to these limited manufacturing facilities could severely impact the clinical development, marketing approval and potential future commercialization of our product candidates.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. Furthermore, if we breach or are perceived to breach our contractual obligations or otherwise default under our agreements with third parties, or if we otherwise have contractual disputes with such third parties, it may lead to adverse outcomes, including potential delays, unforeseen expenses, or the termination of those contracts. We do not currently have a second source for certain required materials used for the manufacture of finished product. If our current manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products could delay, prevent or impair our development and potential future commercialization efforts.

Evaluation of our product candidates in investigator-sponsored clinical trials (ISTs) may expose us to additional risks that could impair the development of our product candidates.

We are currently supporting an IST with Memorial Sloan Kettering Cancer Center to evaluate SER-155 in patients with immune checkpoint related enterocolitis, and may in the future support other ISTs for our product candidates that are designed and managed by independent investigators or institutions. While we believe these clinical trials have the potential to provide supportive data that may further the development of our product candidates, we do not directly control the clinical development process, including, but not limited to, the initiation, enrollment, safety reporting, or conduct of these trials. As a result, ISTs may be subject to significant delays, fail to comply with GCPs or other regulatory requirements, be terminated prematurely by the investigator or applicable IRBs or ethics committees, or produce data that is not useful for, or acceptable to, regulatory authorities for purposes of obtaining regulatory approval. ISTs may also identify safety or tolerability concerns that could adversely affect the development of our product candidates, including through the imposition of clinical holds, or otherwise subject us to liability. Moreover, if the data from any ISTs differ from the data we have observed in our sponsored clinical studies, such differences could potentially require us to conduct additional clinical trials or otherwise delay or prevent regulatory approval from the FDA or other regulatory authorities. Any of these factors could adversely impact our reputation, delay our development timelines, or negatively affect our development and commercialization efforts.

We have limited experience manufacturing our product candidates commercially, and we cannot assure you that we can manufacture our product candidates in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

We have manufacturing facilities at our Cambridge, Massachusetts locations where we conduct process development, scale-up activities, the manufacture of active components for our biotherapeutic candidates, and quality control testing. We additionally utilize third-party contract manufacturers and test labs to perform product packaging and additional quality control testing. We may or may not utilize existing facilities and third-party vendors for future production, including to support commercial scale supply. We have no experience in manufacturing our product candidates to meet potential market demands and we may not be able to develop commercial-scale manufacturing facilities that are adequate to produce materials for commercial use. The FDA and other comparable foreign regulatory authorities must, pursuant to inspections that are conducted after submitting a BLA or relevant foreign marketing submission, confirm that the manufacturing processes for the product meet cGMP or similar regulatory requirements outside the United States. We have not yet had our manufacturing facilities inspected for our product candidates.

The equipment and facilities employed in the manufacture of pharmaceuticals are subject to stringent qualification requirements by regulatory agencies, including validation of facility, equipment, systems, processes and analytics. We may be subject to lengthy delays and expense in conducting validation studies, if we can meet the requirements at all.

Risks Related to Our Product Candidates and Other Legal Matters

Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, hospitals, third-party payors and others in the medical community necessary for commercial success.

Even if any of our product candidates receive marketing approval, our product candidates may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates (if and when they are approved) do not achieve an adequate level of acceptance, we may not become profitable. The degree of market acceptance of any of our product candidates, if approved, will depend on a number of factors, including:

- their efficacy, safety and other potential advantages compared to alternative treatments;
- the clinical indications for which such products are approved;
- our ability to offer them for sale at competitive prices;
- their convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our product candidates;
- the prevalence and severity of their side effects and their overall safety profiles;
- any restrictions on the use of our products, if and when approved, together with other medications;
- interactions of our products, if and when approved, with other medicines patients are taking; and
- the ability of patients to take our products, if and when approved.

If we are unable to establish effective sales, marketing and distribution capabilities or enter into agreements with third parties with such capabilities, we may not be successful in commercializing any of our product candidates if and when they are approved.

We have employees with experience in sales and marketing, but we have limited sales or marketing infrastructure and, as a company, have little experience in the sale, marketing, and distribution of pharmaceutical products. To achieve commercial success for any other product for which we obtain marketing approval, we will need to establish a sales and marketing organization and we may not be successful in doing so.

In the future, we expect to build a focused sales and marketing infrastructure, or certain components of such infrastructure, if we were to market our product candidates, if and when they are approved in the United States and potentially elsewhere. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay the launch of any approved product. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we or any collaborators cannot retain or reposition sales and marketing personnel.

Factors that may inhibit efforts to commercialize our product candidates, if and when approved, include:

- inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

Outside the United States, we intend to rely and may increasingly rely on third parties to sell, market and distribute our product candidates, if and when approved. We may not be successful in entering into arrangements with such third parties or may be unable to do so on terms that are favorable to us. In addition, our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates, if and when they are approved, effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug and biologic products is highly competitive and is characterized by rapid and substantial technological development and product innovations. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are aware of a number of large pharmaceutical and biotechnology companies, as well as smaller, early-stage companies, that are pursuing the development or commercialization of products, including live biotherapeutics, for disease indications we are targeting. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others may be based on entirely different approaches. Potential competitors also include academic institutions, government agencies, not-for-profits, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

These third parties compete with us in recruiting and retaining qualified scientific, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we have or may in the future develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, especially for any competitor developing a live biotherapeutic which will likely share our same regulatory approval requirements. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic or biosimilar products.

Even if we are able to commercialize any of our product candidates, if approved, the products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, any of which would harm our business.

Our ability to commercialize any of our product candidates successfully will depend, in part, on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and impact reimbursement levels.

Obtaining and maintaining adequate reimbursement for our product candidates may be difficult. We cannot be certain if and when we will obtain an adequate level of reimbursement for our product candidates by third-party payors. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review, and increasingly question the coverage of, and challenge the prices charged for, drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval, and potential royalties resulting from the sales of those products may also be adversely impacted.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost treatment approaches and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be reimbursed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control, including possible price reductions, even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically necessary for a specific indication or cost-effective, or that coverage or an adequate level of reimbursement will be available.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and an even greater risk with the commercial sale of any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- decreased demand for product candidates or products, if any;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize products that we develop, if any.

We currently hold $10.0 million in product liability insurance coverage in the aggregate, with a per occurrence limit of $10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials, or if we commence commercialization of our product candidates, if and when approved. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We may face competition from biosimilars, which may have a material adverse impact on the future commercial prospects of our product candidates.

If we obtain approval of any of our product candidates, we may face competition from biosimilars. In the United States, the Biologics Price Competition and Innovation Act, or BPCIA, enacted in 2010 as part of the Patient Protection and Affordable Care Act, created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or biosimilar, to or "interchangeable" with an FDA-approved biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until four years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. This pathway could allow competitors to reference data from innovative biological products 12 years after the time of approval of the innovative biological product, though the FDA may not approve an application relying on such data for a further eight years. This data exclusivity does not prevent another company from developing a product that is highly similar to the innovative product, generating its own data and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the innovator's application to support the biosimilar product's approval.

We believe that any of our product candidates approved as a biological product under a BLA should also qualify for the 12-year period of reference product exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of specific marketplace and regulatory factors that are still developing. For example, in recent years, the FDA has sought to reduce the data required for biosimilar product sponsors to demonstrate biosimilarity to, or interchangeability with, a biologic reference product, which could increase the potential for biosimilar competition.

In the EU, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product but will not be able to get on the market until 10 years after the time of approval of the innovative product. This 10-year marketing exclusivity period can be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our product candidates. If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our product candidates in the EU and many other jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval in foreign countries may differ substantially from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals for our product candidates from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our product candidates in any market.

Any product candidate for which we obtain marketing approval will remain subject to significant post-marketing regulatory requirements and oversight.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to the continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP and similar foreign requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. We and our contract manufacturers will also be subject to continual review and periodic inspections to

assess compliance with cGMP and similar foreign requirements. Accordingly, we, and any collaborator and others with whom we work, must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to specific conditions of approval, including a requirement to implement a risk evaluation and mitigation strategy, which could include requirements for a medication guide, communication plan, or restricted distribution system. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product.

The FDA or other regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. The FDA or other regulatory authorities closely regulates the post-approval marketing and promotion of drugs and biologics to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Violations of the FDA's and other regulatory authorities' restrictions relating to the promotion of prescription drugs by us or any collaborators may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, if a regulatory authority, we or any collaborators later discover previously unknown problems with our product candidates, such as adverse events of unanticipated severity or frequency, problems with manufacturers or manufacturing processes, or failure to comply with regulatory requirements, the regulatory authority may impose restrictions on the products or us and any collaborators, including requiring withdrawal of the product from the market. Any failure by us or any collaborators to comply with applicable regulatory requirements may yield various results, including:

- litigation involving patients taking our products, if and when they are approved;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of products from the market;
- suspension or termination of ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products, if and when they are approved;
- product seizure or detention;
- injunctions; or
- imposition of civil or criminal penalties.

Noncompliance with similar EU requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with U.S. and foreign regulatory requirements regarding the development of products for pediatric populations and the protection of personal health information can also lead to significant penalties and sanctions.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we or any collaborators are found to have improperly promoted off-label uses of approved products, including any of our product candidates that may be approved in the future, we may become subject to significant liability. The FDA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory authorities as reflected in the product's approved labeling. Physicians may nevertheless prescribe a product candidate that is approved in future, if any, to their patients in a manner that is inconsistent with the approved label. If we or any collaborators are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our relationships and any collaborators' relationships with customers, physicians and third-party payors are and will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us or any collaborators to criminal sanctions, civil penalties, exclusion from governmental healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our and any collaborators' current and future arrangements with third-party payors, physicians and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may restrict the business or financial arrangements and relationships through which we market, sell and distribute any other products for which we may in the future obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the False Claims Act, imposes, among other things, criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier. To the extent our patient assistance programs are found to be inconsistent with applicable laws, we may be required to restructure or discontinue such programs, or be subject to other significant penalties;
- HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;
- the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants, and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; manufacturers are required to submit reports to the government by the 90th day of each calendar year; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to our business practices, including but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government (or foreign governments) and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, pricing information or marketing expenditures.

The risk of us or any collaborators being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us or any collaborators for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that we may violate one or more of the requirements.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement, and the curtailment or restructuring of our operations.

Current and future legislation or regulation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may adversely affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, including executive orders, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any product candidates approved for sale. New and changing laws and regulations may also create uncertainty about how such laws and regulations will be interpreted and applied. If we are found to have violated laws and regulations, it could materially adversely affect our business, results of operations and financial condition.

In the United States, the Affordable Care Act, or ACA, was signed into law in 2010. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affects the U.S. pharmaceutical industry.

Among the provisions of the ACA of importance to our business, including without limitation, our ability to commercialize and the prices we may obtain for any product candidates that are approved for sale are the following:

- establishment of a new pathway for approval of lower-cost biosimilars to compete with biologic products, such as those we are developing or commercializing;
- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- extension of manufacturers' Medicaid rebate liability to apply to Medicaid managed care utilization;
- expansion of the entity types eligible for participation in the 340B drug pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, enacted in August 2011, required sequestration that included aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will increase in future years of the sequester. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Drug manufacturers' Medicaid Drug Rebate Program rebate liability was previously capped at 100% of the average manufacturer price for a covered outpatient drug.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. The Inflation Reduction Act, or the IRA, was enacted in 2022. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (which began in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). CMS has published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and the subsequent 15 drugs, which will be first effective in 2027. CMS has published the next set of 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how these proposals will be implemented, these policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for any product candidate that we commercialize. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business.

Individual states in the United States have become increasingly active in enacting laws or implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Some measures are designed to encourage

importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. Some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution.

Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our ability to price our product candidates, if and when they are approved, appropriately, which could negatively impact our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to price our product candidates, if and when they are approved, at what we consider to be a fair or competitive price, generate revenue, attain profitability, or commercialize our product candidates, if approved.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the EU member states, the pricing of certain pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various EU member states and parallel distribution or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. Even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. If coverage and reimbursement of our product candidates, if and when they are approved, are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels that impacts our ability to compete with other products or our ability to recoup our costs of developing our product candidates, our business could be harmed, possibly materially.

Risks Related to Our Intellectual Property

If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions. Prosecution of our patent portfolio is at various stages. We have successfully obtained multiple patents (both U.S. and foreign) in some patent families. In others, prosecution is at an early stage (e.g., provisional or PCT stage). For many patent applications in our portfolio, we have filed national stage applications based on our Patent Cooperation Treaty, or PCT, applications, thereby limiting the jurisdictions in which we can pursue patent protection for the various inventions claimed in those applications. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

We have obtained licenses from third parties and may obtain additional licenses and options in the future. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business.

We have had in the past, and may have in the future, certain funding arrangements. Such funding arrangements impose various obligations on us, including reporting obligations, and may subject certain of our intellectual property, such as intellectual property made using the applicable funding, to the rights of the U.S. government under the Bayh-Dole Act. Any failure to comply with our obligations under a funding arrangement may have an adverse effect on our rights under the applicable agreement or our rights in the applicable intellectual property. Compliance with our obligations or the exercise by the government or other funder of its rights, may limit certain opportunities or otherwise have an adverse effect on our business.

Our patent portfolio currently includes 21 active patent application families (which includes an exclusive license to certain IP from Memorial Sloan Kettering Cancer Center). Of these, 16 applications have been nationalized, three are at the PCT stage, and one is at the provisional stage. To date, we have obtained issuance of 33 U.S. patents (which includes three as licensee). Of the issued U.S. patents, 13 U.S. patents (including one as licensee) have been assigned to Nestlé Health Science as part of its purchase of VOWST. We cannot provide any assurances that any of our pending patent applications will mature into issued patents and, if they do, that such patents or our current patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. For example, we are pursuing claims to therapeutic, binary compositions of certain bacterial populations. Any claims that may issue may provide coverage for such binary compositions and/or their use. However, there can be no assurance that an alternative composition that may fall outside the scope of such claims will not be equally effective. Further, while our product candidates are made up of specific cultivated bacteria, third-party compositions may have greater complexity and variability (e.g., lot to lot variations), and it is possible that a patent claim may provide coverage for some but not all third-party compositions. These and other factors may provide opportunities for our competitors to design around our patents, should they issue.

Moreover, other parties have developed technologies that may be related or competitive to our approach and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming similar methods or by claiming subject matter that could dominate our patent position or cover one or more of our product candidates. In addition, given the on-going prosecution of our portfolio, we continue development of our understanding of how patent offices react to our patent claims and whether they identify prior art of relevance that we have not already considered.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we may license patents were the first to make the inventions claimed or were the first to file. For these and other reasons, the issuance, scope, validity, enforceability and commercial value of our patent rights are subject to a level of uncertainty. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

We may be subject to third-party preissuance submissions of prior art to the United States Patent and Trademark Office, or USPTO, or in a foreign jurisdiction in which our applications are filed, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. For example, on April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to

The University of Tokyo. See "*—Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business*." The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo appealed certain aspects of the Opposition Division's decision, as did we and other opponents. On November 18, 2022, The University of Tokyo requested termination of the appeal proceeding and revocation of its patent. On December 19, 2022, the Opposition Division officially terminated the appeal proceeding, and European Patent No. 2 575 835 B1 has been revoked in its entirety.

An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. The issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering biotechnological and pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if issued, a patent's validity, inventorship, ownership or enforceability is not conclusive. Accordingly, rights under any existing patent or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our pending patent applications, if issued, will include claims having a scope sufficient to protect any products or product candidates;
- any of our pending patent applications will issue as patents at all;
- we will be able to successfully commercialize any of our product candidates, if approved, before our relevant patents expire;
- we were the first to make the inventions covered by any existing patent and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe or design around our patents;
- others will not use pre-existing technology to effectively compete against us;
- any of our patents, if issued, will be found to ultimately be valid and enforceable;
- third parties will not compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we will be able to obtain and/or maintain necessary or useful licenses on reasonable terms or at all;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe upon the patents or proprietary rights of others.

Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings, may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

If we are unable to protect the confidentiality of our trade secrets and know-how, our business and competitive position may be harmed.

In addition to seeking patents for some of our technology and product candidates, we also utilize our trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular the first to file provisions, became effective on March 16, 2013. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Thus, for our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. Moreover, some of the patent applications in our portfolio will be subject to examination under the pre-Leahy- Smith Act law and regulations, while other patent applications in our portfolio will be subject to examination under the law and regulations, as amended by the Leahy-Smith Act. This introduces additional complexities into the prosecution and management of our portfolio.

In addition, the Leahy-Smith Act limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge any issued patent in the USPTO. These provisions apply to all of our U.S. patents, even those filed before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a federal court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims because it may be easier for them to do so relative to challenging the patent in a federal court action. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. From time to time, the Supreme Court, other federal courts, Congress, or the USPTO, may change the standards of patentability and any such changes could have a negative impact on our business.

A number of cases decided by the Supreme Court have involved questions of when claims reciting abstract ideas, laws of nature, natural phenomena and/or natural products are eligible for a patent, regardless of whether the claimed subject matter is otherwise novel and inventive. These cases include *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 12-398 (2013); *Alice Corp. v. CLS Bank International*, 573 U.S. 13-298 (2014); and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 10-1150 (2012). In response to these cases, the USPTO has issued guidance to the examining corps.

The USPTO first issued a memorandum reflecting the USPTO's interpretation of the cases related to patent eligibility of natural products on March 4, 2014, which it subsequently revised and expanded upon in several additional updates now incorporated into its Manual of Patent Examination Procedure. The USPTO's interpretation of the case law and new guidelines for examination may influence, possibly adversely, prosecution and defense of certain types of claims in our portfolio.

In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on these and other decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change or be interpreted in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that may issue to us in the future. In addition, these events may adversely affect our ability to defend any patents that may issue in procedures in the USPTO or in courts.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of any collaborators, to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. For example, on August 20, 2024, Vedanta Biosciences, Inc. and The University of Tokyo filed a complaint against us and Nestlé S.A., Nestlé Health Science S.A., Nestlé Health Science US Holdings, Inc. and SPN in the United States District Court for the District of Delaware alleging that the making, sale and use of VOWST infringes on U.S. Patent Nos. 9,433,652, 9,662,381, 9,808,519, 10,555,978, and 11,090,343. The complaint seeks unspecified damages, fees, expenses and injunctive relief. We believe the complaint is without merit and intend to defend ourself vigorously against the claims. While we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our technology or our product candidates, or use of our product candidates do not infringe third-party patents.

We are aware of numerous patents and pending applications owned by third parties in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology or our product candidates. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of our product candidates, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies or our product candidates or the use of our product candidates. We are aware of several pending patent applications containing one or more claims that could be construed to cover some of our product candidates or technology, should those claims issue in their original form or in the form presently being pursued. In addition, we are aware of third-party patent families that include issued and allowed patents, including in the United States, including claims that, if valid and enforceable, could be construed to cover some of our product candidates or their methods of use. On April 25, 2017, we filed a notice of opposition in the European Patent Office challenging the validity of a patent issued to The University of Tokyo and requesting that it be revoked in its entirety for the reasons set forth in our opposition. The oral proceedings were held at the European Patent Office on February 18, 2019 and the Opposition Division required The University of Tokyo to narrow the scope of the claims of the patent. The University of Tokyo appealed certain aspects of the Oppositions Division's decision, as did we and other opponents. On November 18, 2022, The University of Tokyo requested termination of the appeal proceeding and revocation of its patent. On December 19, 2022, the Opposition Division officially terminated the appeal proceeding, and European Patent No. 2 575 835 B1 has been revoked in its entirety.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates, or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future. If we were to challenge the validity of an issued U.S. patent in court, such as an issued U.S. patent of potential relevance to some of our product candidates or methods of use, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. There is no assurance that a court would find in our favor on questions of infringement or validity.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found or believe there is a risk we may be found, to infringe a third party's intellectual property rights, we could be required or may choose to obtain a license from such third party to continue developing and marketing our product candidates and technology. However, we may not be able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our product candidates. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign, or rename, some or all of our product candidates or other brands to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

Issued patents covering our product candidates could be found invalid or unenforceable or could be interpreted narrowly if challenged in court.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. If we initiated legal proceedings against a third party to enforce a patent, if and when issued, covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement, or failure to claim patent eligible subject matter. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Moreover, even if not found invalid or unenforceable, the claims of our patents could be

construed narrowly or in a manner that does not cover the allegedly infringing technology in question. Such a loss of patent protection would have a material adverse impact on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and, in some jurisdictions, during the pendency of a patent application. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

It is our policy to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, contractors and advisors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, even if we have a consulting agreement in place with an academic advisor pursuant to which such academic advisor is required to assign any inventions developed in connection with providing services to us, such academic advisor may not have the right to assign such inventions to us, as it may conflict with his or her obligations to assign all such intellectual property to his or her employing institution.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may also engage advisors and consultants who are concurrently employed at universities or other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, advisors or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party's former or current employer or in violation of an agreement with another party. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our employees, consultants, advisors and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person's obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we

need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than in the United States, assuming that rights are obtained in the United States and assuming that rights are pursued outside the United States. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For each of the patent families that we believe provide coverage for our product candidates, we decide whether and where to pursue protection outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, even if we do elect to pursue patent rights outside the United States, we may not be able to obtain relevant claims and/or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Additionally, Europe's Unified Patent Court, or UPC, may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. Although this new court has been implemented to provide more certainty and efficiency to patent enforcement throughout Europe, it will also provide our competitors with a new forum to use to centrally challenge our patents if opted into the UPC, rather than having to seek invalidity or non-infringement decisions on a country-by-country basis. It will be several years before the scope of patent rights that will be recognized and the strength of patent remedies that will be provided is known.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive

and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

If our ability to obtain and, if obtained, enforce our patents to stop infringing activities is inadequate, third parties may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Accordingly, our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

Risks Related to Our Operations

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

On February 27, 2026, the board of directors appointed Richard N. Kender, a current member of the board of directors, to serve as Executive Chair of the Board and as Interim Chief Executive Officer of the Company, Matthew Henn, Ph.D., the Company's Chief Scientific Officer, to the additional role of President, and Kelly Brady, M.S., the Company's Senior Vice President, Clinical Development, to the role of Executive Vice President, Chief Operating Officer, each effective March 2, 2026. As a result of the appointment of Mr. Kender as Interim Chief Executive Officer, Thomas J. DesRosier and Marella Thorell ceased serving as Co-Presidents and Co-Chief Executive Officers of the Company as of March 2, 2026. Mr. DesRosier continues to serve as the Company's Executive Vice President and Chief Legal Officer. On October 22, 2026, Ms. Thorell resigned as Executive Vice President and Chief Financial Officer, effective November 15, 2026, and Mr. Kender will serve as our principal financial officer and principal accounting officer on an interim basis.

Management transitions may create uncertainty and involve a diversion of resources and management attention, be disruptive to our daily operations or impact public or market perception, any of which could negatively impact our ability to operate effectively or execute our strategies and result in a material adverse impact on our business, financial condition, results of operations or cash flows. If we are unable to execute an orderly transition, our business may be adversely affected. Furthermore, the success of our business is dependent on the continuation of an experienced and talented management team. If we were to lose the benefit of the experience, efforts, and abilities of any of our key executives or members of senior management, our business could be adversely affected.

We are highly dependent on our Interim CEO, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and potential future commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for hiring of scientific and clinical personnel from universities and research institutions.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy and execution. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

On September 23, 2025, we announced that we implemented cost reduction actions, including decreasing our workforce by approximately 25%. We decreased the workforce by an additional 30% in February 2026 as part of additional cost reduction measures taken to extend our cash runway. These measures could result in personnel attrition beyond our planned reduction in headcount or reduce employee morale, which could in turn adversely impact productivity, including through a loss of continuity, loss of accumulated knowledge and/or inefficiency during transitional periods, or our ability to attract highly skilled employees.

If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

A variety of risks associated with operating internationally could materially adversely affect our business.

We currently have limited international operations, but our business strategy incorporates potentially expanding internationally if any of our product candidates receive regulatory approval. We have conducted clinical studies internationally in the past, and will

likely in the future conduct clinical studies in other countries as well. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, including tariffs, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our product candidates in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- global macroeconomic conditions, including a continued increase in inflation rates or interest rates, labor shortages, supply chain shortages, disruptions and instability in the banking industry and other parts of the financial services sector, or other economic, political or legal uncertainties or adverse developments;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations;
- terrorism and/or political instability, unrest and wars, such as the conflicts involving Ukraine and Russia or Israel and its surrounding regions, which could delay or disrupt our business, and if such political unrest escalates or spills over to or otherwise impacts additional regions it could heighten many of the other risk factors included in this Item 1A;
- natural disasters (including as a result of severe weather events, climate change, or otherwise), which could cause significant damage to the infrastructure upon which our business operations rely, and the timing, nature or severity of which we may be unable to prepare for;
- economic instability, outbreak of disease or epidemics, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

We have excess leased space that may adversely affect our financial condition and results of operations.

Following the sale of our VOWST Business, the completion of the TSA, and our cost reduction actions, we have significantly reduced our workforce and manufacturing footprint. In June 2026, we entered into the First Amendment to Lease with respect to our space at 101 Cambridge Park Drive, Cambridge, Massachusetts, which reduced our leased space from approximately 82,714 to 36,882 rentable square feet. In July 2026, we entered into the Third Amendment to Lease and Termination Agreement with respect to our space at 200 Sidney Street, Cambridge, Massachusetts, which provided for the surrender of approximately 21,295 rentable square feet and the revision of the lease expiration date for the remaining approximately 47,341 rentable square feet from January 2031 to December 31, 2026. We continue to have excess capacity under our remaining lease obligations that exceeds our current and anticipated operational needs. We remain obligated to make rental and other payments under these leases regardless of whether we utilize the leased space. Our near-term lease obligations, including under these lease amendments require us to make substantial cash payments that reduce the cash available to fund our research and development programs, clinical trials, and other operational needs.

Current commercial real estate market conditions, including elevated vacancy rates and declining demand for certain types of office and laboratory space, may further limit any sublease opportunities that remain available to us. Even if we are able to sublease any excess space, we would remain primarily liable to the landlord under the underlying leases, and any default by a subtenant could result in additional costs and liabilities to us.

In addition, we have been required to, and may in the future be required to recognize impairment charges with respect to right-of-use assets associated with leased properties that are no longer being fully utilized. Any such impairment charges could have a material adverse effect on our results of operations and financial condition.

The costs associated with our remaining lease obligations, termination payments, and impairment charges, combined with any inability to sublease such space or potential impairment charges, could materially and adversely affect our liquidity, cash flows, financial condition, and results of operations, and could limit our ability to invest in the advancement of SER-155 and our other pipeline programs.

Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity.

In the ordinary course of our business, we collect and store sensitive data, including personally identifiable information, intellectual property and proprietary business information owned or controlled by ourselves or our employees and other third parties. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers, and as a result a number of third-party vendors may or could have access to our confidential information. These applications and data encompass a wide variety of business-critical information, including research and development information, customer information, commercial information and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate or unauthorized access, use, modification or disclosure, and the risk of our being unable to adequately monitor and audit and modify our controls over our confidential information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data or otherwise process it on our behalf. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take reasonable measures to protect sensitive data from unauthorized access, use or disclosure, our information technology systems and those of our third-party service providers, strategic partners and other contractors or consultants are vulnerable to attack, damage and interruption from computer viruses and malware (e.g., ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who continue to work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques, including artificial intelligence ("AI") that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Additionally, any integration of artificial intelligence in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges.

We and certain of our service providers are from time to time subject to cyberattacks and security attempts or incidents that threaten the confidentiality, integrity, and availability of our information technology systems and confidential information. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. If we or our third-party vendors were to experience a significant cybersecurity breach of our or their information technology systems or data, the costs associated with the investigation and remediation could be material. Any such real or perceived unauthorized access or use, breach, or other loss of confidential information could also result in regulatory scrutiny, reputational harm, legal claims or proceedings (including class actions), and liability under federal or state laws that protect the privacy of personal information, and regulatory enforcement, including penalties or fines. Notice of breaches may be required to affected individuals or state, federal or foreign regulators, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such notifications could be costly, harm our reputation and our ability to compete. Although we have implemented security measures to prevent unauthorized access, such data is currently accessible through multiple channels, and there is no guarantee that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and data from breach. Additionally, we cannot guarantee that any costs and liabilities incurred in relation to an attack or incident will be covered by our existing insurance policies or that applicable insurance will be available to us in the future on economically reasonable terms or at all.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and

enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our results of operations, financial performance and business.

In the U.S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, or collectively HIPAA, imposes privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. Most healthcare providers, including research institutions from which we obtain clinical trial information, are subject to privacy and security regulations promulgated under HIPAA. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not regulated under HIPAA. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act or collectively, the CCPA, requires covered businesses that process personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt-out of certain disclosures of their personal information; and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may also be required. Similar laws have been enacted in other states reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Furthermore, the Federal Trade Commission, or FTC, and many State Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, we may be subject to the European Union General Data Protection Regulation ("EU GDPR") and to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the "UK GDPR") (the EU GDPR and UK GDPR together referred to as the "GDPR"). The GDPR imposes strict requirements for processing the personal data of individuals within the European Economic Area, or EEA or UK, or in the context of our activities within the EEA and the UK. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million / £17.5 million or 4% of the annual global revenues of the noncompliant undertaking, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the EU states that reliance on the standard contractual clauses, or SCCs - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis.

We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by

regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we operate our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Our business may be affected by the evolving regulatory framework for AI Technologies.

We use AI and machine learning (collectively, "AI Technologies") throughout our business, and are making modest investments in this area. The regulatory framework for AI Technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of our AI Technologies.

It is possible that new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expend resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

Acquisitions, dispositions, joint ventures, or other strategic alternatives could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We may from time to time acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses, investments in complementary businesses, dispose of assets, or pursue other strategic alternatives. We have not made any acquisitions to date, and our ability to do so successfully is unproven. On September 30, 2024, we completed the sale of our VOWST Business to SPN, which included all inventory and equipment, certain patents and patent applications, know-how, trade secrets, trademarks, domain names, marketing authorizations and related rights, documents, materials, business records and data and contracts that are used or held for use primarily in the development, commercialization and manufacturing of VOWST. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies or disposed assets or businesses;
- additional exposure to cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure;
- difficulties retaining or integrating acquired personnel, technologies and operations;
- diversion of management time and focus from operating our business to transaction, acquisition integration, or disposition-related challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired or disposed businesses; and
- inability to develop a sales force for any additional product candidates.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any acquisition, disposition, or any other transaction or strategic alternative may not materialize. Future acquisitions, dispositions, or alternatives could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, amortization expenses, or write-offs of goodwill, and may not achieve their intended benefits, any of which

could harm our financial condition and our business. We cannot predict the number, timing or size of any transactions, or the effect that any such transactions might have on our operating results, our business, or our financial condition.

We have in the past been subject to securities class action litigation and may be subject to similar or other litigation in the future, which may harm our business.

Securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. On September 28, 2016, a purported stockholder filed a putative class action lawsuit in the U.S. District Court for the District of Massachusetts against us entitled Mariusz Mazurek v. Seres Therapeutics, Inc., et.al. alleging false and misleading statements and omissions about our clinical trials for our then product candidate SER-109 in our public disclosures between June 25, 2015 and July 29, 2016. Although this lawsuit has been dismissed by the court, should we face similar or other litigation again, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. In addition, the uncertainty of a pending lawsuit or potential filing of additional lawsuits could lead to more volatility and a reduction in our stock price.

We are subject to complex and changing laws and regulations, which exposes us to potential liabilities, increased costs and other adverse effects on our business.

We are subject to complex and changing laws, regulations, and executive orders, and compliance with these laws and regulations and executive orders is onerous and expensive. New and changing laws, regulations, and executive orders can adversely affect our business by increasing our costs, limiting the Company's ability to pursue or offer a product candidate or product, and requiring changes to our business. New and changing laws, regulations, and executive orders can also create uncertainty about how such laws and regulations will be interpreted and applied. Regulatory changes and other actions that materially adversely affect our business may be announced with little or no advance notice and we may not be able to effectively mitigate all adverse impacts from such measures. Differing interpretations of such legal obligations can expose us to significant fines, government investigations, litigation and reputational harm. If we are found to have violated laws, regulations, or executive orders, it could materially adversely affect our business, reputation, results of operations and financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials such as human stool. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our ability to use our net operating loss carryforwards and research and development credits to offset future taxable income or income tax liabilities, respectively, may be subject to certain limitations.

As of December 31, 2025, we had net operating loss carryforwards, or NOLs, of $616.4 million for federal income tax purposes and $597.8 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal NOLs subject to expiration begin to expire in various amounts in 2035. Our federal NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration, but may generally only be used to offset 80% of taxable income in years beginning after December 31, 2020. Our state NOLs also begin to expire in various amounts in 2035. As of December 31, 2025, we also had federal and state research and development and other tax credit carryforwards of approximately $46.2 million and $10.0 million, respectively, net of uncertain tax position reserves, available to reduce future income tax liabilities, if any. Our federal and state tax credit carryforwards begin to expire in various amounts in 2031 and 2028, respectively. The federal research and development tax credit carryforwards include an orphan drug credit carryforward of $25.9 million. These NOLs and tax credit carryforwards could expire unused, to the extent subject to expiration, and be unavailable to offset future taxable income or income tax liabilities, respectively.

In addition, in general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an “ownership change” is subject to limitations on its ability to use its pre-change NOLs and tax credit carryforwards to offset future taxable income and income taxes, respectively. For these purposes, an ownership change generally occurs where the aggregate change in stock ownership of one or more stockholders or groups of stockholders owning at least 5% of a corporation’s stock exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We have experienced ownership changes in the past, per a Section 382 study performed through December 31, 2024. We believe that none of our existing tax assets will expire unused as a result of the calculated limitations resulting from such ownership changes. However, we may have experienced additional ownership changes since December 31, 2024, and we may experience ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. If we have undergone additional ownership changes, or if we undergo ownership changes in the future, our ability to use our NOLs and tax credit carryforwards could be further limited. For these reasons, we may not be able to use a material portion of our NOLs or tax credit carryforwards, even if we attain profitability. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets.

Risks Related to Our Common Stock

We have in the past and may again in the future receive a notice of the failure to satisfy a continued listing rule from Nasdaq.

In November 2024, we received written notice from Nasdaq notifying us that the bid price for our common stock had closed below the $1.00 Bid Price Requirement for continued inclusion on The Nasdaq Global Select Market. Though we regained compliance with the Bid Price Requirement in a timely manner, if in the future our common stock again closes below the $1.00 per share minimum bid price required by Nasdaq for 30 consecutive business days, we would again receive another notice of non-compliance with Nasdaq's listing standards and face the risk of delisting.

If, in the future, our common stock fails to meet the Bid Price Requirement and we have effected a reverse stock split within the prior one-year period, we will not be eligible for any compliance period to address the bid price deficiency and would be issued a delisting determination rather than be granted a compliance period. Under these circumstances, we could appeal the delisting determination to a Nasdaq hearing panel, during which time any suspension or delisting action will ordinarily be stayed. If we were eligible for a compliance period, there can also be no assurance that we would regain compliance with the Bid Price Requirement during the 180-day compliance period, secure a second 180-day period to regain compliance, maintain compliance with the other Nasdaq listing requirements, or be successful in appealing any delisting determination.

If our common stock is delisted in the future, it is unlikely that we will be able to list our common stock on another national securities exchange on a timely basis or at all, and, as a result, we expect our securities would be quoted on an OTC market. If this were to occur, we and our stockholders could face significant material adverse consequences, including limited availability of market quotations and analyst coverage for our common stock, and reduced liquidity for the trading of our securities. Delisting also could result in, among other things, a loss of investor confidence or interest in strategic transactions or opportunities, us being subject to regulation in each state in which we offer our securities, and difficulty in recruiting and retaining personnel through equity incentive awards.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately 29% of our outstanding voting stock as of December 31, 2025. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We have also registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a "smaller reporting company" as defined under the rules promulgated under the Exchange Act. We will remain a smaller reporting company until the fiscal year following the determination that both (i) the value of our voting and non-voting common shares held by non-affiliates is more than $250.0 million measured on the last business day of our second fiscal quarter and (ii) our annual revenues are more than $100.0 million during the most recently completed fiscal year and the value of our voting and nonvoting common shares held by non-affiliates is $700.0 million or more as measured on the last business day of our second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, or supplemental financial information.

We have elected to take advantage of certain of the reduced reporting obligations, and may in the future take advantage of these or others. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because the Board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions include those establishing:

- a classified Board with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our Board;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our Board to elect a director to fill a vacancy created by the expansion of the Board or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our Board;
- the ability of our Board to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our Board to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the Board, the chief executive officer, the president or the Board, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our Board or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware, subject to certain exceptions, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders and our bylaws designate the federal district courts of the United States as the exclusive forum for actions arising under the Securities Act of 1933,

as amended, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. In addition, our bylaws provide that the federal district courts of the United States are the exclusive forum for any complaint raising a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the provisions of our restated certificate of incorporation and bylaws described above.

We believe these choice of forum provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation or bylaws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provisions contained in our restated certificate of incorporation or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

General Risk Factors

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price is likely to be volatile. Furthermore, the stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their common stock. The market price for our common stock may be influenced by many factors, including:

- our ability to develop, execute and realize the benefits of strategic plans including accessing capital through potential business development and/or achieving overall financing goals;
- our requirement for additional capital to fund our operations following the first quarter of 2027;
- our ability to realize the benefits of the Transaction with SPN;
- our continued compliance with stock exchange listing standards;
- the success of competitive products or technologies;
- actual or anticipated changes in our growth rate relative to our competitors;
- results of clinical trials of our product candidates or those of our competitors;
- the success of any potential future commercialization efforts;
- developments related to any future collaborations;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and may make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

If securities or industry analysts issue an adverse or misleading opinion regarding our business, our common stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We will continue to incur costs as a result of being a public company, and our management will continue to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, we expect that these rules and regulations will continue to make it more difficult and more expensive for us to maintain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a non-accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the Securities and Exchange Commission or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Failure to keep up with evolving and conflicting laws, regulations, trends and stakeholder expectations relating to environmental, social and governance, or ESG, practices or reporting could adversely impact our reputation, share price and access to and cost of capital or otherwise adversely impact our business.

Certain institutional investors, investor advocacy groups, investment funds, creditors and other influential financial market participants, as well as governments, regulators, customers, patients, employees and other stakeholders or third parties, have become increasingly focused on companies' ESG practices, including the impact of business on the environment. Certain organizations also provide ESG ratings, scores and benchmarking studies that assess companies' ESG practices. Although there are no universal standards for such ratings, scores or benchmarking studies, they are used by some investors to inform their investment and voting decisions. It is possible that our future stockholders or organizations that report on, rate or score ESG practices will not be satisfied with our ESG strategy or performance. Unfavorable press about or ratings or assessments of our ESG strategies or practices, regardless of whether or not we comply with applicable legal requirements, may lead to negative investor sentiment toward us, which may hinder the Company's access to capital.

Our reputation could be damaged if we do not, or are perceived not to, meet evolving stakeholder demand with respect to ESG matters, which could adversely affect our business, financial condition, profitability and cash flows. We may be criticized for our lack of ESG initiatives or goals or perceived as not taking sufficient action or for taking too much action in connection with any of these matters. In turn, we may take certain or terminate other actions to respond to evolving demand by regulators, governmental officials, investors, employees and other stakeholder; however, such actions may be costly or be subject to numerous conditions that are outside our control, and we cannot guarantee that we will meet these goals or targets or that such actions will have the desired effect even if met.

There has been an increase in litigation related to corporate diversity, equity and inclusion programs. Relatedly, both advocates and opponents to certain environmental and social matters are increasingly resorting to a range of activism forms, including media campaigns, shareholder proposals, and litigation, to advance their perspectives. To the extent we are subject to such litigation, activism or pressure, we may be required to incur costs or it may otherwise adversely impact our business or reputation.

Additionally, we and/or other parties in our value chain are subject to, or are expected to be subject to additional climate and other ESG-related obligations arising from legislation and regulation in the United States, the European Union and other jurisdictions, including new reporting requirements, even as the availability and quality of the information that may be required to comply with such laws and regulations remains limited. We expect our compliance costs with these laws, regulations, and reporting requirements to increase in the future, and any failure, or perceived failure, by us to adhere to such laws, regulations, and reporting requirements, or meet evolving and varied stakeholder expectations and standards, could harm our business, reputation, financial condition, and operating results.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

a) Disclosure in lieu of reporting on a Current Report on Form 8-K.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

As previously reported, on October 22, 2026, Marella Thorell resigned from her positions as Executive Vice President and Chief Financial Officer of the Company, effective November 15, 2026 (the “Effective Date”).

On November 1, 2026, the Board appointed Richard Kender, the Company’s Executive Chair and Interim Chief Executive Officer and principal executive officer, to serve as the Company’s principal financial officer and principal accounting officer and succeed Ms. Thorell in these capacities, effective as of the Effective Date. Mr. Kender will continue to serve as the Company’s Executive Chair and Interim Chief Executive Officer and principal executive officer, and he will not receive any additional compensation for his role as principal financial officer and principal accounting officer during this period.

A description of Mr. Kender’s business experience can be found under the section entitled "Executive Officers" in the Company’s definitive proxy statement on Schedule 14A, filed with the Securities and Exchange Commission on April 27, 2026, and which biography is incorporated by reference herein.

The Company and Mr. Kender have previously entered into the Company’s standard indemnification agreement for executive officers. There are no family relationships between Mr. Kender and any director or executive officer of the Company that would be required to be disclosed pursuant to Item 401(d) of Regulation S-K, and Mr. Kender does not have a material interest in any transaction that is required to be disclosed under Item 404(a) of Regulation S-K.

Advisory Agreement with Marella Thorell

In connection with her resignation, on November 2, 2026, the Company and Ms. Thorell entered into an advisory agreement (the "Advisory Agreement") pursuant to which Ms. Thorell will provide advisory services to the Company from the Effective Date through March 31, 2027, unless terminated earlier by either party on 15 business days' prior written notice, in exchange for an hourly fee of $500.00. Ms. Thorell is expected to provide the Company with up to 20 hours of advisory services per month. Ms. Thorell's performance of advisory services will constitute continued service to the Company for purposes of the vesting and exercisability of her outstanding Company stock options.

Resignation of Robert Rosiello

On October 30, 2026, Robert Rosiello resigned from his position as a member of the board of directors of the Company and on the committees on which he serves, effective October 30, 2026. Mr. Rosiello's departure is not due to any disagreement with the Company on any matter relating to the Company’s operations, policies or practices.

b) Material changes to the procedures by which security holders may recommend nominees to the board of directors.

None.

c) Insider trading arrangements and policies.

During the three months ended September 30, 2026, no director or "officer" (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation, filed on July 1, 2015	8-K	001-37465	3.1	7/1/15	
3.2	Certificate of Amendment to Restated Certificate of Incorporation of Seres Therapeutics, Inc., dated June 27, 2023	8-K	001-37465	3.1	6/28/23	
3.3	Certificate of Amendment to Restated Certificate of Incorporation of Seres Therapeutics, Inc., dated April 5, 2024	8-K	001-37465	3.1	4/8/24	
3.4	Certificate of Amendment to Restated Certificate of Incorporation of Seres Therapeutics, Inc., dated April 21, 2025	8-K	001-37465	3.1	4/22/25	
3.5	Amended and Restated Bylaws	8-K	001-37465	3.1	1/2/24	
10.1	Third Amendment to Lease and Termination Agreement, dated July 31, 2026, by and between Seres Therapeutics, Inc. and BMR-Sidney Research Campus, LLC	8-K	001-37465	10.1	8/4/26	
10.2	Stock Issuance Agreement, dated July 31, 2026, by and between Seres Therapeutics, Inc. and BMR-Sidney Research Campus, LLC	8-K	001-37465	10.2	8/4/26	
10.3	Advisory Agreement, dated November 2, 2026, by and between Marella Thorell and Seres Therapeutics, Inc.					
31.1	Rule 13a-14(a)/15d-14(a) Certification of Interim Chief Executive Officer					*
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Interim Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
101.INS	Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.
** Furnished herewith.

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 thereunto duly authorized.

SERES THERAPEUTICS, INC.

Date: November 4, 2026

By: /s/ Marella Thorell
Marella Thorell
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.3

Advisory Agreement

This Advisory Agreement ("Agreement") is made by and between Marella Thorell ("Executive") and Seres Therapeutics, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party").

WHEREAS, in connection with Executive's resignation from employment with the Company effective November 15, 2026 (the "Date of Resignation"), the Parties wish to enter into this Agreement.

NOW, THEREFORE, in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Advisory Services.

(a) General. During the period commencing on the Date of Resignation and ending on March 31, 2027 or, if earlier, the date on which Executive's advisory relationship with the Company is terminated as provided in Section 1(e) below (the "Advisory Period"), Executive shall serve in the capacity of a non-employee advisor to the Company and provide such advisory services as are reasonably requested by the Company (the "Advisory Services"). For the avoidance of doubt, the Parties anticipate Executive will provide the Advisory Services for up to [20] hours per month at such times as reasonably requested by the Company.

(b) Advisory Fees. In consideration of the Advisory Services, Executive shall be eligible for the following compensation and benefits:

(i) Advisory Fee. The Company will pay to Executive an advisory fee in the amount of $500.00 per hour for each hour spent by Executive in the performance of the Advisory Services for the Company (the "Advisory Fee"). The Advisory Fee will be payable within 30 days of the end of each month upon presentation of a Company approved invoice by Executive, fully detailing the time spent and tasks performed by Executive. Invoices should reference this Agreement and should be submitted to: Accounts Payable, Seres Therapeutics, Inc, 101 Cambridgepark Drive, Cambridge, MA 02140 or via email at billing@seresthrerapeutics.com with a copy to Kristen Grogan at kgrogan@serestherapeutics.com.

(ii) Treatment of Equity Awards. Subject to and conditioned upon (A) Executive providing the Advisory Services through the Advisory Period to the good-faith satisfaction of the Company and (B) Executive's continued compliance with Section 2, with respect to those outstanding Company stock options and restricted stock units held by Executive on the Date of Resignation (the "Company Equity Awards"), the Advisory Services shall constitute continued service to the Company such that (1) the Company Equity Awards will continue to vest and, as applicable, become exercisable, during the Advisory Period, and (2) with respect to those Company Equity Awards that are stock options, such stock options will remain exercisable during the Advisory Period, and the post-termination exercise period of such stock options will not commence until the expiration of the Advisory Period.

(c) Expenses. During the Advisory Period, the Company will reimburse Executive for reasonable and necessary out-of-pocket expenses incurred by Executive in the performance of the Advisory Services, provided such out-of-pocket expenses are approved in

advance by an officer of the Company and further are supported by reasonable documentation. Such expenses will include reasonable travel expenses of Executive to the Company's offices.

(d) No Other Compensation. Except as expressly described in Section 1(b), there shall be no other fees, salary or compensation paid to Executive for the Advisory Services during the Advisory Period.

(e) Termination of Advisory Relationship. The advisory relationship established in accordance with this Section 1 may be terminated by the Company or Executive at any time and for any reason with fifteen (15) business days' prior written notice to the other party.

(f) Independent Contractor Status. The Parties acknowledge and agree that during the Advisory Period, Executive shall be engaged solely as an independent contractor and neither Executive nor any principal, employee or contractor of Executive shall be construed to be an employee of the Company in any matter under any circumstances or for any purposes whatsoever. Nothing in this Agreement shall establish an agency, partnership, joint venture or employee relationship between the Company and Executive, and Executive shall not represent herself as an employee or officer of the Company. The Company and Executive agree and acknowledge that neither Party hereto renders legal, tax or accounting advice to the other Party. Without limiting the generality of the foregoing, (i) the Company shall not pay, on the account of Executive or any principal, employee or contractor of Executive, any taxes required under the law to be paid with respect to employees and shall not withhold any monies from the Advisory Fees or expenses payable pursuant to Section 1 of this Agreement for income or employment tax purposes, (ii) the Company shall not provide Executive or any principal, employee or contractor of Executive with, and no such individual shall be eligible to receive from the Company under any Company plan, any benefits, including without limitation, any pension, health, welfare, retirement, workers' compensation or other insurance benefits, , and (iii) Executive shall be solely responsible for, and shall indemnify and hold the Company harmless from, all taxes arising in connection with any Advisory Fees or other compensation paid to Executive under this Section 1, including without limitation any and all federal, state, local and foreign income and employment taxes.

2. Post-Termination Obligations.

(a) Executive reaffirms Executive's continuing obligations under the Employee Non-Competition, Non-Solicitation Confidentiality and Assignment Agreement between Executive and the Company dated as of February 20, 2024 and, without limiting the foregoing, Executive remakes the non-competition covenants set forth in the Employee Non-Competition, Non-Solicitation Confidentiality and Assignment Agreement as if set forth herein.

(b) In addition, Executive agrees to refrain from Disparaging (as defined below) the Company and its affiliates, including their respective services, technologies, practices, directors and officers. The Company agrees to instruct its officers and directors to refrain from Disparaging Executive. Nothing in this Section shall preclude any Party from making truthful statements that are reasonably necessary to comply with applicable law, regulation or legal process, or to defend or enforce a Party's rights under this Agreement or the Employment Agreement. For purposes of this Agreement, "Disparaging" means making remarks, comments or

statements, whether written or oral, that impugn the character, integrity, reputation or abilities of the individual or entity being disparaged.

3. Company Property. All materials and property provided to Executive (including all samples, equipment, prototypes, devices, reports, communications, drawings, notes, and analyses), or produced by Executive, in connection with the performance of services under this Agreement shall be the exclusive property of Company. Executive will keep in Executive's custody and control any such materials or property that Executive receives or develops, and will return the same to Company upon the termination of the Consultation Period or at Company's request. Executive agrees to treat such materials and property with at least the same degree of confidentiality and care that it keeps Executive's own materials and property. No materials containing proprietary information may be thrown in the trash unless the same are shredded.

4. Representations and Warranties. Executive represents and warrants that Executive has no duty or obligation to any third party with respect to the Services. Executive further represents and warrants that the services covered by this Agreement are not in violation of any other agreement or obligation by which Executive is bound.

5. Notice. All notices required or permitted under this Agreement shall be in writing and shall be deemed effective upon personal delivery or upon deposit in the United States Post Office, by registered or certified mail, postage prepaid, addressed:

If to Company:
Seres Therapeutics, Inc.
101 Cambridgepark Drive
Cambridge, MA 02140

Attn: Richard Kender,
With a copy to Seres Legal Department at legal@serestherapeutics.com

If to Executive:
Marella Thorell
6164 Argos Drive
Blue Bell, PA 19422

6. Miscellaneous. This Agreement constitutes the entire agreement between the parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement. This Agreement may be amended or modified only by a written instrument executed by both Company and the Executive. This Agreement shall be construed, interpreted and enforced in accordance with the laws of the Commonwealth of Massachusetts. This Agreement shall be binding upon, and inure to the benefit of, both parties and their respective successors and assigns, including any corporation with which, or into which, Company may be merged or which may succeed to its assets or business, *provided, however*, that the obligations of the Executive are personal and shall not be assigned by Executive. If any of the provisions of this Agreement is found to be unenforceable or prohibited by any applicable law, such provision shall be ineffective only to the extent of such unenforceability or prohibition

without invalidating the remainder of such provision or the remaining provisions of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date set forth below.

Dated: November 2, 2026

/s/ Marella Thorell
Marella Thorell

SERES THERAPEUTICS, INC.

Dated: November 2, 2026

By: /s/ Richard Kender
Name: Richard Kender
Title: Executive Chair and Interim CEO

Exhibit 31.1

CERTIFICATIONS

I, Richard N. Kender, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Seres Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2026

By: /s/ Richard N. Kender
Richard N. Kender
Executive Chair and Interim Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Marella Thorell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Seres Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2026

By: /s/ Marella Thorell
Marella Thorell
Executive Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard N. Kender, Executive Chair and Interim Chief Executive Officer of Seres Therapeutics, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2026 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 4, 2026

/s/ Richard N. Kender
Richard N. Kender
Executive Chair and Interim Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Marella Thorell, Executive Vice President, Chief Financial Officer of Seres Therapeutics, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2026 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 4, 2026

/s/ Marella Thorell
Marella Thorell
Executive Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)