

**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, 2020

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**

(State or other jurisdiction of  
incorporation or organization)

**200 Sidney Street - 4th Floor**

**Cambridge, MA**

(Address of principal executive offices)

**27-4326290**

(I.R.S. Employer  
Identification No.)

**02139**

(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 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, 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

Non-accelerated filer

Emerging growth company

Accelerated filer

Small reporting 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 3, 2020, the registrant had 91,248,238 shares of common stock, \$0.001 par value per share, outstanding.

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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, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, the impact of the COVID-19 pandemic on our business, operations and liquidity, and the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements 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 Quarterly 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 Quarterly Report titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- our status as a clinical-stage company and our expectation to incur losses in the future;
- our future capital needs and our need to raise additional funds;
- our ability to build a pipeline of product candidates and develop and commercialize drugs;
- our unproven approach to therapeutic intervention;
- the unexpected impact of the COVID-19 pandemic on our operations, the continuity of our business, including our preclinical studies and clinical trials, general economic conditions and ability to raise additional capital;
- our ability to enroll patients in clinical trials, timely and successfully complete those trials and receive necessary regulatory approvals;
- the timing of completion of enrollment and availability of data from our ongoing clinical trials;
- the expected timing of filings with regulatory authorities related to our product candidates;
- our ability to maintain our manufacturing facilities and to receive or manufacture sufficient quantities of our product candidates;
- our ability to protect and enforce our intellectual property rights;
- federal, state, and foreign regulatory requirements, including U.S. Food and Drug Administration regulation of our product candidates;
- our ability to obtain and retain key executives and attract and retain qualified personnel; and
- our ability to successfully manage our growth.

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.

## 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, 2020	December 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 207,326	\$ 65,126
Short term investments	90,588	29,690
Prepaid expenses and other current assets	6,703	3,588
Accounts receivable	3,393	1,785
Total current assets	<u>308,010</u>	<u>100,189</u>
Property and equipment, net	14,729	19,495
Operating lease assets	9,664	11,356
Restricted investments	1,400	1,400
Long term investments	22,398	—
Total assets	<u>\$ 356,201</u>	<u>\$ 132,440</u>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 6,201	\$ 4,859
Accrued expenses and other current liabilities	11,318	10,884
Operating lease liabilities	4,950	4,456
Deferred revenue - related party	16,517	20,960
Deferred revenue	6,784	4,834
Total current liabilities	<u>45,770</u>	<u>45,993</u>
Note payable, net of discount	24,977	24,648
Operating lease liabilities, net of current portion	11,894	15,676
Deferred revenue, net of current portion - related party	82,826	89,111
Deferred revenue, net of current portion	1,695	4,834
Other long-term liabilities	987	502
Total liabilities	<u>168,149</u>	<u>180,764</u>
Commitments and contingencies (Note 11)		
Stockholders' deficit:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2020 and December 31, 2019; no shares issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at September 30, 2020 and December 31, 2019; 91,214,536 and 70,143,252 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	91	70
Additional paid-in capital	718,483	411,255
Accumulated other comprehensive income	2	—
Accumulated deficit	(530,524)	(459,649)
Total stockholders' equity (deficit)	<u>188,052</u>	<u>(48,324)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 356,201</u>	<u>\$ 132,440</u>

*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**  
(unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
<b>Revenue:</b>				
Collaboration revenue - related party	\$ 80	\$ 4,840	\$ 10,728	\$ 21,909
Grant revenue	1,337	85	2,907	791
Collaboration revenue	—	2,106	2,016	4,183
Total revenue	<u>1,417</u>	<u>7,031</u>	<u>15,651</u>	<u>26,883</u>
<b>Operating expenses:</b>				
Research and development expenses	23,861	18,317	65,703	59,109
General and administrative expenses	7,551	5,897	20,180	18,966
Restructuring expenses	—	—	—	1,492
Total operating expenses	<u>31,412</u>	<u>24,214</u>	<u>85,883</u>	<u>79,567</u>
Loss from operations	<u>(29,995)</u>	<u>(17,183)</u>	<u>(70,232)</u>	<u>(52,684)</u>
<b>Other (expense) income:</b>				
Interest income	100	335	333	744
Interest expense	(730)	—	(2,165)	—
Other income	345	439	1,189	439
Total other (expense) income, net	<u>(285)</u>	<u>774</u>	<u>(643)</u>	<u>1,183</u>
Net loss	<u>\$ (30,280)</u>	<u>\$ (16,409)</u>	<u>\$ (70,875)</u>	<u>\$ (51,501)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.23)</u>	<u>\$ (0.93)</u>	<u>\$ (0.99)</u>
Weighted average common shares outstanding, basic and diluted	<u>83,531,617</u>	<u>69,944,068</u>	<u>75,914,361</u>	<u>52,143,492</u>
Net loss	<u>(30,280)</u>	<u>(16,409)</u>	<u>(70,875)</u>	<u>(51,501)</u>
<b>Other comprehensive loss:</b>				
Unrealized gain on investments, net of tax of \$0	1	7	2	7
Total other comprehensive gain	<u>1</u>	<u>7</u>	<u>2</u>	<u>7</u>
Comprehensive loss	<u>\$ (30,279)</u>	<u>\$ (16,402)</u>	<u>\$ (70,873)</u>	<u>\$ (51,494)</u>

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit)
	Shares	Par Value				
<b>Balance at December 31, 2018</b>	40,936,735	\$ 41	\$ 341,284	\$ (389,370)	\$ —	\$ (48,045)
Issuance of common stock upon exercise of stock options	38,125	—	120	—	—	120
Issuance of common stock upon vesting of RSUs, net of tax withholdings	73,500	—	153	—	—	153
Issuance of common stock under ESPP plan	46,472	—	207	—	—	207
Stock-based compensation expense	—	—	2,065	—	—	2,065
Net loss	—	—	—	(24,333)	—	(24,333)
<b>Balance at March 31, 2019</b>	<u>41,094,832</u>	<u>41</u>	<u>343,829</u>	<u>(413,703)</u>	<u>—</u>	<u>(69,833)</u>
Issuance of common stock from public offering, net of commissions, underwriting discounts and offering costs	28,818,578	29	60,498	—	—	60,527
Stock-based compensation expense	—	—	2,097	—	—	2,097
Net loss	—	—	—	(10,759)	—	(10,759)
<b>Balance at June 30, 2019</b>	<u>69,913,410</u>	<u>70</u>	<u>406,424</u>	<u>(424,462)</u>	<u>—</u>	<u>(17,968)</u>
Issuance of common stock upon exercise of stock options	52,000	—	25	—	—	25
Issuance of common stock under ESPP plan	28,542	—	89	—	—	89
Stock-based compensation expense	—	—	2,037	—	—	2,037
Unrealized gain on investments	—	—	—	—	7	7
Net loss	—	—	—	(16,409)	—	(16,409)
<b>Balance at September 30, 2019</b>	<u>69,993,952</u>	<u>\$ 70</u>	<u>\$ 408,575</u>	<u>\$ (440,871)</u>	<u>\$ 7</u>	<u>\$ (32,219)</u>

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Par Value				
<b>Balance at December 31, 2019</b>	70,143,252	\$ 70	\$ 411,255	\$ (459,649)	\$ —	\$ (48,324)
Issuance of common stock from at the market equity offering	1,230,531	1	4,177	—	—	4,178
Issuance of common stock upon exercise of stock options	110,967	1	59	—	—	60
Issuance of common stock upon vesting of RSUs, net of tax withholdings	110,000	—	120	—	—	120
Issuance of common stock under ESPP plan	76,317	—	249	—	—	249
Stock-based compensation expense	—	—	1,959	—	—	1,959
Unrealized loss on investments	—	—	—	—	(10)	(10)
Net loss	—	—	—	(19,881)	—	(19,881)
<b>Balance at March 31, 2020</b>	<u>71,671,067</u>	<u>72</u>	<u>417,819</u>	<u>(479,530)</u>	<u>(10)</u>	<u>(61,649)</u>
Issuance of common stock from at the market equity offering	3,430,453	3	14,845	—	—	14,848
Issuance of common stock upon exercise of stock options	30,314	—	15	—	—	15
Stock-based compensation expense	—	—	1,914	—	—	1,914
Unrealized gain on investments	—	—	—	—	11	11
Net loss	—	—	—	(20,714)	—	(20,714)
<b>Balance at June 30, 2020</b>	<u>75,131,834</u>	<u>75</u>	<u>434,593</u>	<u>(500,244)</u>	<u>1</u>	<u>(65,575)</u>
Issuance of common stock from public offering, net of commissions, underwriting discounts and offering costs	12,075,000	12	243,736	—	—	243,748
Issuance of common stock from Securities Purchase Agreement, net of offering costs - related party	959,002	1	19,899	—	—	19,900
Issuance of common stock from at the market equity offering	1,126,697	1	5,745	—	—	5,746
Issuance of common stock upon exercise of stock options	1,828,027	2	12,048	—	—	12,050
Issuance of common stock upon vesting of RSUs, net of tax withholdings	15,000	—	—	—	—	—
Issuance of common stock under ESPP plan	78,976	—	213	—	—	213
Stock-based compensation expense	—	—	2,249	—	—	2,249
Unrealized gain on investments	—	—	—	—	1	1
Net loss	—	—	—	(30,280)	—	(30,280)
<b>Balance at September 30, 2020</b>	<u>91,214,536</u>	<u>\$ 91</u>	<u>\$ 718,483</u>	<u>\$ (530,524)</u>	<u>\$ 2</u>	<u>\$ 188,052</u>

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,	
	2020	2019
<b>Cash flows from operating activities:</b>		
Net loss	\$ (70,875)	\$ (51,501)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,122	6,199
Depreciation and amortization expense	5,069	5,803
Non-cash operating lease cost	1,693	1,683
Accretion of discount on investments	(105)	(87)
Amortization of debt issuance costs	329	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,054)	2,772
Accounts receivable	(1,608)	(1,717)
Deferred revenue	(11,917)	(17,709)
Accounts payable	1,032	(1,857)
Operating lease liabilities	(3,288)	(3,164)
Accrued expenses and other current and long-term liabilities	919	(2,895)
Net cash used in operating activities	<u>(75,683)</u>	<u>(62,473)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(365)	(772)
Purchases of investments	(125,995)	(34,407)
Sales and maturities of investments	42,804	8
Net cash used in investing activities	<u>(83,556)</u>	<u>(35,171)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from public offering of common stock, net of commissions, underwriting discounts and offering costs	244,020	60,527
Proceeds from Securities Purchase Agreement, net of issuance costs - related party	20,000	—
Proceeds from exercise of stock options	12,065	145
Proceeds from issuance of common stock and restricted common stock	120	153
Proceeds from at the market equity offering, net of commissions	24,772	—
Issuance of common stock under ESPP plan	462	296
Net cash provided by financing activities	<u>301,439</u>	<u>61,121</u>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>142,200</b>	<b>(36,523)</b>
Cash, cash equivalents and restricted cash at beginning of period	65,126	85,933
Cash, cash equivalents and restricted cash at end of period	<u>\$ 207,326</u>	<u>\$ 49,410</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 1,843	\$ —
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Issuance costs from public offering included in accounts payable and accrued expenses	\$ 272	\$ —
Securities Purchase Agreement issuance costs included in accounts payable and accrued expenses - related party	\$ 100	\$ —
Proceeds from exercise of stock options in prepaid expenses and other current assets	\$ 61	\$ —
Reduction of right-of-use assets and lease liability from operating lease modifications or reassessments	\$ —	\$ 154
Property and equipment purchases included in accounts payable and accrued expenses	\$ —	\$ 54

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



**SERES THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Amounts in thousands, except share and per share data)**  
**(Unaudited)**

**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 microbiome therapeutics platform company developing 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 dysbiotic microbiome to a non-disease state. The Company’s lead product candidate, SER-109, is designed to prevent further recurrences of *Clostridioides difficile* infection (formerly *Clostridium difficile* infection) (“CDI”), a debilitating infection of the colon, in patients who have received antibiotic therapy for recurrent CDI by treating the dysbiosis of the colonic microbiome. If approved by the U.S. Food and Drug Administration (“FDA”), we believe SER-109 will be a first-in-field oral microbiome drug. SER-287 and SER-301 are being developed by the Company to treat ulcerative colitis (“UC”). In addition, using its microbiome therapeutics platform, the Company is also developing product candidates to treat diseases where the microbiome is implicated, including SER-401, a microbiome therapeutic candidate for use with checkpoint inhibitors (“CPI’s”) in patients with metastatic melanoma and SER-155, a rationally designed, fermented therapeutics candidate to prevent mortality due to gastrointestinal infections, bacteremia and graft versus host disease (“GvHD”) in immunocompromised patients, including in patients receiving allogeneic hematopoietic stem cell transplantation (“allo-HSCT”) and solid organ transplants. The Company continues to evaluate microbiome pharmacokinetic and pharmacodynamic data from its SER-262 Phase 1b study and other completed clinical trials to inform the design of drug candidates in the pipeline, inform clinical trial design, and to determine next steps in the development of SER-262 to treat an initial recurrence of CDI. The Company is also using its reverse translation microbiome therapeutics platforms to conduct research on various indications, including pathogen infection and antibiotic resistant bacteria, inflammatory and immune diseases, cancer, and metabolic diseases.

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. Product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities.

The Company’s product candidates are in development. 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 candidates developed will obtain necessary government regulatory approval, or that any approved products 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. 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.

On August 10, 2020, the Company reported positive topline results from its pivotal Phase 3 ECOSPOR III study evaluating SER-109 for recurrent CDI. The Company is actively enrolling patients in its SER-109 open-label study, which also admits patients with a single recurrence of CDI, to expand the safety database to meet the FDA guidance of at least 300 patients.

On August 12, 2020, the Company completed an underwritten public offering in which it sold 10,500,000 shares of its common stock at a public offering price of \$21.50 per share. In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 1,575,000 shares of its common stock at the public offering price, less underwriting discounts and commissions, which the underwriters exercised in full. The Company received aggregate net proceeds from the offering of approximately \$243,748 after deducting underwriting discounts and commissions and offering expenses payable by the Company.

On August 12, 2020, the Company entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”) with Société des Produits Nestlé S.A. (“Nestlé”) for the sale of 959,002 shares of its common stock at a purchase price of \$20.855 per share (the “concurrent placement”). The Company received aggregate net proceeds from the concurrent placement of approximately \$19,900 after deducting offering expenses payable by the Company.

Under Accounting Standards Update (“ASU”) 2014-15, *Presentation of Financial Statements—Going Concern* (Subtopic 205-40) (“ASC 205-40”), the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the date that the financial statements are issued. As required by ASC 205-40, this evaluation shall initially not take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued.

As of September 30, 2020, the Company had an accumulated deficit of \$530,524 and cash, cash equivalents and investments of \$320,312. For the nine months ended September 30, 2020, the Company incurred a loss of \$70,875 and used \$75,683 of cash in operations. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. The Company expects that its cash, cash equivalents and short and long-term investments at September 30, 2020 of \$320,312 will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12-months from issuance of the financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company is eligible to receive contingent milestone payments under its license and collaboration agreement with Nestec Ltd. (“NHS”), an affiliate of Nestlé Health Science US Holdings, Inc. (“Nestlé Health Science”) and Nestlé, both significant stockholders of the Company, if certain development milestones are achieved. However, these milestones are uncertain and there is no assurance that the Company will receive any of them. Until such time, if ever, as the Company can generate substantial product revenue, the Company will finance its cash needs through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships, or marketing, distribution or licensing arrangements with third parties. The Company may not be able to obtain funding on acceptable terms, or at all. If the Company is unable to raise additional funds as and when needed, it would have a negative impact on the Company’s financial condition, which may require the Company to delay, reduce or eliminate certain research and development activities and reduce or eliminate discretionary operating expenses, which could constrain the Company’s ability to pursue its business strategies.

### ***Unaudited Interim Financial Information***

The accompanying unaudited condensed consolidated financial statements as of September 30, 2020 and for the three and nine months ended September 30, 2020 and 2019 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, 2019 included in the Company’s annual report on Form 10-K for the fiscal year ended December 31, 2019, which was filed with the SEC on March 2, 2020 (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, 2019 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 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, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

## **2. Summary of Significant Accounting Policies**

The significant accounting policies and estimates used in preparation of the condensed consolidated financial statements are described in the Company’s audited financial statements as of and for the year ended December 31, 2019, 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, 2020.

## 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 consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including revenue, operating expenses, clinical trials and employee-related amounts, will depend on future developments that are highly uncertain, including new information that may emerge concerning COVID-19 and the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. We have made estimates of the impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods. Actual results could differ from the Company's estimates.

## Net Loss per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and unvested restricted stock.

The restricted stock units granted by the Company entitle the holder of such awards to ordinary cash dividends paid to substantially all holders of the Company's common stock, as if such shares were outstanding common shares at the time of the dividend. The dividends are paid in cash or shares of common stock when the applicable restricted stock unit vests. However, the unvested restricted stock units are not entitled to share in the residual net assets (deficit) of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

The following potential common shares, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2020	2019
Stock options to purchase common stock	9,802,633	8,258,031
Unvested restricted stock units	—	145,900
Shares issuable under ESPP	3,748	13,171
Total common stock equivalents	<u>9,806,381</u>	<u>8,417,102</u>

## Recently Issued Accounting Standards

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). This standard modifies certain disclosure requirements on fair value measurements. This standard became effective for the Company on January 1, 2020 and did not have a material impact on the Company's disclosures.

In November 2018 the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This standard makes targeted improvements for collaborative arrangements as follows:

- Clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, Revenue from Contracts with Customers, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements;
- Adds unit-of-account guidance to ASC 808, Collaborative Arrangements, to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606; and
- Precludes a company from presenting transactions with collaborative participants that are not directly related to sales to third parties with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer.

This standard became effective for the Company on January 1, 2020 and did not have a material impact on the Company’s condensed consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes may result in earlier recognition of credit losses. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*, which narrowed the scope and changed the effective date for non-public entities for ASU 2016-13. The FASB subsequently issued supplemental guidance within ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief* (“ASU 2019-05”). ASU 2019-05 provides an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. For public entities that are Securities and Exchange Commission filers, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, ASU 2016-13 is effective for annual periods beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. This standard will be effective for the Company on January 1, 2023. The Company is currently evaluating the potential impact that this standard may have on its condensed consolidated financial statements and related disclosures.

### 3. Fair Value Measurements

The following tables present the Company’s fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements as of September 30, 2020 Using:			
	Level 1	Level 2	Level 3	Total
<b>Cash equivalents:</b>				
Money market funds	\$ 18,846	\$ —	\$ —	\$ 18,846
Commercial paper	—	4,998	—	4,998
Government securities	—	10,000	—	10,000
<b>Investments:</b>				
Commercial paper	—	6,245	—	6,245
Corporate bonds	—	2,021	—	2,021
Government securities	—	104,720	—	104,720
	<u>\$ 18,846</u>	<u>\$ 127,984</u>	<u>\$ —</u>	<u>\$ 146,830</u>

	Fair Value Measurements as of December 31, 2019 Using:			
	Level 1	Level 2	Level 3	Total
<b>Cash equivalents:</b>				
Money market funds	\$ 25,510	\$ —	\$ —	\$ 25,510
Commercial paper	—	4,243	—	4,243
Corporate bonds	—	4,900	—	4,900
<b>Investments:</b>				
Commercial paper	\$ —	\$ 11,957	\$ —	\$ 11,957
Corporate bonds	—	17,733	—	17,733
	<u>\$ 25,510</u>	<u>\$ 38,833</u>	<u>\$ —</u>	<u>\$ 64,343</u>

Money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. Commercial paper, corporate bonds and government securities were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. There were no transfers between Level 1 or Level 2 during the three and nine months ended September 30, 2020 and 2019.

As of September 30, 2020 and December 31, 2019 the Company held a restricted investment of \$1,400, which represent a certificate of deposit that is classified as Level 2 in the fair value hierarchy.

#### 4. Investments

Investments by security type consisted of the following at September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
<b>Investments:</b>				
Commercial paper	\$ 6,245	\$ —	\$ —	\$ 6,245
Corporate bonds	2,021	—	—	2,021
Government securities	104,718	4	(2)	104,720
	<u>\$ 112,984</u>	<u>\$ 4</u>	<u>\$ (2)</u>	<u>\$ 112,986</u>

  

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
<b>Investments:</b>				
Commercial Paper	\$ 11,957	\$ —	\$ —	\$ 11,957
Corporate Bonds	17,732	3	(2)	17,733
	<u>\$ 29,689</u>	<u>\$ 3</u>	<u>\$ (2)</u>	<u>\$ 29,690</u>

Investments with original maturities of less than 90 days are included in cash and cash equivalents on the condensed consolidated balance sheets and are not included in the table above. Investments with maturities of less than 12 months are considered current and those investments with maturities greater than 12 months are considered non-current assets.

Excluded from the table above in a restricted investment of \$1,400 as the cost approximates current fair value.

The amortized cost and fair value of investments in commercial paper, corporate bonds and government securities by contractual maturity, as of September 30, 2020 were as follows (in thousands):

	Available-for-Sale	
	Cost	Fair Value
Due in 1-year or less	\$ 90,586	\$ 90,588
Due after 1-year through 5-years	22,398	22,398
	<u>\$ 112,984</u>	<u>\$ 112,986</u>

#### 5. Property and Equipment, Net

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

	September 30, 2020	December 31, 2019
Laboratory equipment	\$ 15,656	\$ 15,140
Computer equipment	2,874	2,874
Furniture and office equipment	1,033	1,033
Leasehold improvements	27,977	27,977
Construction in progress	—	213
	<u>47,540</u>	<u>47,237</u>
Less: Accumulated depreciation and amortization	<u>(32,811)</u>	<u>(27,742)</u>
	<u>\$ 14,729</u>	<u>\$ 19,495</u>

Depreciation and amortization expense was \$1,576, \$5,069, \$1,876 and \$5,803 for the three and nine months ended September 30, 2020 and 2019, respectively.

## 6. Accrued Expenses and Other Current Liabilities

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

	September 30, 2020	December 31, 2019
Development and clinical manufacturing costs	\$ 6,443	\$ 5,605
Payroll and payroll-related costs	3,921	4,609
Facility and other	954	670
	<u>\$ 11,318</u>	<u>\$ 10,884</u>

## 7. Restructuring

In February 2019, the Company implemented corporate changes to focus its resources on advancing its clinical-stage therapeutic candidates. As a result, the Company concentrated on obtaining results from the SER-109 Phase 3 study for recurrent CDI, completing the SER-287 Phase 2b study in mild-to-moderate UC, advancing the SER-401 Phase 1b study, in collaboration with the Parker Institute for Cancer Immunotherapy and MD Anderson Cancer Center, to evaluate augmenting CPI response in patients with metastatic melanoma, advancing clinical activities for a SER-301 Phase 1b study, and advancing SER-155 into clinical development. In connection with the prioritization of these therapeutic candidates, the Company made changes to its management team and reduced headcount by approximately 30 percent.

No restructuring charges were recorded during the three and nine months ended September 30, 2020. During the nine months ended September 30, 2019, the Company recorded charges of \$1,492, related to severance and other termination benefits. Of that amount, the Company paid \$206 during the three months ended September 30, 2019 and \$1,101 during the nine months ended September 30, 2019. There are no remaining unpaid liabilities related to restructuring charges as of September 30, 2020.

## 8. Note Payable

On October 29, 2019 (the "Closing Date"), the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc. ("Hercules") pursuant to which a term loan in an aggregate principal amount of up to \$50,000 (the "Term Loan Facility") is available to the Company in three tranches, subject to certain terms and conditions. The first tranche of \$25,000 was advanced to the Company on the Closing Date. The Company did not meet the milestone requirements for the second tranche under the Term Loan Facility, and as such, the additional amount up to \$12,500 is not available for the Company to borrow. The third tranche, which allows the Company to borrow an additional \$12,500, will be available upon Hercules' approval on or prior to June 30, 2021.

Advances under the Term Loan Facility will bear interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 4.40%, and (ii) 9.65%. The Company will make interest only payments through December 1, 2021. The interest only period may be extended to June 1, 2022 upon satisfaction of certain milestones. Following the interest only period, the Company will repay the principal balance and interest of the advances in equal monthly installments through November 1, 2023.

The Company may prepay advances under the Loan Agreement, in whole or in part, at any time subject to a prepayment charge (the "Prepayment Premium") equal to: (a) 3.0 % of amounts so prepaid, if such prepayment occurs during the first year following the Closing Date; (b) 2.0% of the amount so prepaid, if such prepayment occurs during the second year following the Closing Date, and (c) 1.0% of the amount so prepaid, if such prepayment occurs after the second year following the Closing Date.

Upon prepayment or repayment of all or any of the term loans under the Term Loan Facility, the Company will pay (in addition to any Prepayment Premium) an end of term charge of 4.85% of the aggregate funded amount under the Term Loan Facility. With respect to the first tranche, an end of term charge of \$1,213 will be payable upon any prepayment or repayment. To the extent that the Company is provided additional advances under the Term Loan Facility, the 4.85% end of term charge will be applied to any such additional amounts.

The Term Loan Facility is secured by substantially all of the Company's assets, other than the Company's intellectual property. The Company has agreed to not pledge or secure its intellectual property to others.

Upon issuance, the first tranche was recorded as a liability with an initial carrying value of \$24,575, net of debt issuance costs. The initial carrying value will be accreted to the repayment amount, which includes the outstanding principal plus the end of term charge, through interest expense using the effective interest rate method over the term of the debt. The effective interest rate is 11.47%. The carrying value of the debt, which is classified as a non-current liability on the Company's consolidated balance sheet, is \$24,977 and \$24,648 as of September 30, 2020 and December 31, 2019, respectively.

As of September 30, 2020 the future principal payments due under the arrangement, excluding interest and the end of term charge, are as follows (in thousands):

Year Ending December 31,	Principal
2020 (remaining 6 months)	\$ —
2021	949
2022	11,970
2023	12,081
<b>Total</b>	<b>\$ 25,000</b>

During the three and nine months ended September 30, 2020, the Company recognized \$730 and \$2,165 of interest expense related to the Loan Agreement, which is reflected in interest expense on the condensed consolidated statement of operations and comprehensive loss.

## 9. Common Stock and Stock-Based Awards

### Common Stock

In August 2020, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Cowen and Company, LLC and Piper Sandler & Co., as representatives of the several underwriters named therein (collectively, the "Underwriters"), in connection with the issuance and sale by the Company in a public offering of 10,500,000 shares of the Company's common stock at a public offering price of \$21.50 per share, less underwriting discounts and commissions, pursuant to an effective shelf registration statement on Form S-3 (Registration No. 333-244401) and a related prospectus supplement filed with the Securities and Exchange Commission (the "SEC" and such public offering, the "offering"). Under the terms of the Underwriting Agreement, the Company granted the Underwriters an option exercisable for 30 days to purchase up to an additional 1,575,000 shares of its common stock at the public offering price, less underwriting discounts and commissions, which the underwriters exercised in full.

In August 2020, the Company entered into the Securities Purchase Agreement with Nestlé for the sale by the Company of 959,002 shares of the Company's common stock at a purchase price of \$20.855 per share (the "concurrent placement"). The Company received aggregate net proceeds from the concurrent placement of approximately \$19,900 after deducting offering expenses payable by the Company. The consummation of the concurrent placement was contingent upon the closing of the offering and the satisfaction of certain other customary conditions. The shares were offered and sold to Nestlé pursuant to an effective registration statement on Form S-3 (File No. 333-237033) and a related prospectus supplement filed with the SEC.

In November 2019, the Company entered into a sales agreement (the, "2019 Sales Agreement"), with Cowen to sell shares of its common stock with aggregate gross sales proceeds of up to \$25,000, from time to time, through an ATM under which Cowen acts as sales agent. On March 18, 2020, in connection with filing an updated registration statement on Form S-3 (File No. 333-237033), the Company entered into a Sales Agreement (the "2020 Sales Agreement"), with Cowen on substantially the same terms as the 2019 Sales Agreement and terminated the 2019 Sales Agreement. From January 1, 2020 to September 30, 2020 the Company sold 5,787,681 shares of common stock under the 2019 Sales Agreement and the 2020 Sales Agreement, as applicable, at an average price of approximately \$4.40 per share, raising aggregate net proceeds of approximately \$24,772 after deducting an aggregate commission of approximately 3%.

## Stock Options

The following table summarizes the Company's stock option activity since December 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2019	8,310,683	\$ 10.36	7.01	\$ 3,427
Granted	4,574,365	4.59		
Exercised	(1,969,308)	6.15		
Forfeited	(1,113,107)	10.66		
Outstanding as of September 30, 2020	<u>9,802,633</u>	<u>\$ 8.47</u>	<u>7.93</u>	<u>\$ 196,033</u>
Options exercisable as of September 30, 2020	<u>3,264,289</u>	<u>\$ 14.60</u>	<u>5.91</u>	<u>\$ 46,335</u>

The weighted average grant-date fair value of stock options granted during the three and nine months ended September 30, 2020 and 2019 was \$18.12, \$3.03, \$2.12 and \$5.67 per share, respectively.

During the three months ended March 31, 2019, the Company granted performance-based stock options to employees for the purchase of an aggregate of 1.1 million shares of common stock with a grant date fair value of \$4.58 per share. These stock options are exercisable only upon achievement of specified performance targets. As of September 30, 2020, none of these options were exercisable because none of the specified performance targets had been achieved. Because achievement of the specified performance targets was not deemed probable as of September 30, 2020, the Company did not record any expense for these stock options from the dates of issuance through September 30, 2020.

## Restricted Stock Units

The Company has granted restricted stock units with time-based vesting conditions. The table below summarizes the Company's restricted stock unit activity since December 31, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2019	130,000	\$ 8.86
Granted	—	—
Forfeited	(5,000)	\$ 2.29
Vested	(125,000)	\$ 9.12
Unvested restricted stock units as of September 30, 2020	<u>—</u>	<u>\$ —</u>

## 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 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development expenses	\$ 1,368	\$ 1,033	\$ 3,358	\$ 3,574
General and administrative expenses	881	1,004	2,764	2,625
	<u>\$ 2,249</u>	<u>\$ 2,037</u>	<u>\$ 6,122</u>	<u>\$ 6,199</u>



## 10. Collaboration Revenue

### *NHS Collaboration Agreement*

#### *Summary of Agreement*

In January 2016, the Company entered into a collaboration and license agreement with NHS (“License Agreement”) for the development and commercialization of certain product candidates for the treatment and management of CDI and inflammatory bowel disease, or IBD, including UC and Crohn’s disease. The License Agreement supports the development of the Company’s portfolio of products for CDI and IBD in markets outside of the United States and Canada (the “Licensed Territory”). The Company has retained full commercial rights to its entire portfolio of product candidates with respect to the United States and Canada.

Under the License Agreement, the Company granted to NHS an exclusive, royalty-bearing license to develop and commercialize, in the Licensed Territory, certain products based on its microbiome technology that are being developed for the treatment of CDI and IBD, including SER-109, SER-262, SER-287 and SER-301 (collectively, the “NHS Collaboration Products”). The License Agreement sets forth the Company’s and NHS’ respective obligations for development, commercialization, regulatory and manufacturing and supply activities for the NHS Collaboration Products with respect to the licensed fields and the Licensed Territory.

Under the License Agreement, NHS agreed to pay the Company an upfront cash payment of \$120,000, which the Company received in February 2016. The Company is eligible to receive up to \$285,000 in development milestone payments, \$375,000 in regulatory payments and up to an aggregate of \$1,125,000 for the achievement of certain commercial milestones related to the sales of NHS Collaboration Products. NHS also agreed to pay the Company tiered royalties, at percentages ranging from the high single digits to high teens, of net sales of NHS Collaboration Products in the Licensed Territory.

Under the License Agreement, the Company is entitled to receive a \$20,000 milestone payment from NHS following initiation of a SER-287 Phase 2 study and a \$20,000 milestone payment from NHS following the initiation of a SER-287 Phase 3 study. In November 2018, the Company entered into a letter agreement with NHS which modified the License Agreement to address the current clinical plans for SER-287. Pursuant to the letter agreement, the Company and NHS agreed that following initiation of the SER-287 Phase 2b study, the Company would be entitled to receive \$40,000 in milestone payments from NHS, which represent the milestone payments due to the Company for the initiation of a SER-287 Phase 2 study and a Phase 3 study. The SER-287 Phase 2b study was initiated and the \$40,000 of milestone payments were received in December 2018. The letter agreement also provides scenarios under which NHS’ reimbursement to the Company for certain Phase 3 development costs would be reduced or delayed depending on the outcomes of the SER-287 Phase 2b study.

#### *Accounting Analysis*

The Company assessed the License Agreement in accordance with ASC 606—*Revenue From Contracts with Customers* (“ASC 606”) and concluded that NHS is a customer. The Company identified the following promises under the contract: (i) a license to develop and commercialize the NHS Collaboration Products in the Licensed Territory, (ii) obligation to perform research and development services, (iii) participation on a joint steering committee, and (iv) manufacturing services to provide clinical supply to complete future clinical trials. In addition, the Company identified a contingent obligation to perform manufacturing services to provide commercial supply if commercialization occurs, which is contingent upon regulatory approval. This contingent obligation is not a performance obligation at inception and has been excluded from the initial allocation as it represents a separate buying decision at market rates, rather than a material right in the contract. The Company assessed the promised goods and services to determine if they are distinct. Based on this assessment, the Company determined that NHS cannot benefit from the promised goods and services separately from the others as they are highly interrelated and therefore not distinct. Accordingly, the promised goods and services represent one combined performance obligation and the entire transaction price will be allocated to that single combined performance obligation.

At contract inception, the Company determined that the \$120,000 non-refundable upfront amount constituted the entirety of the consideration to be included in the transaction price as the development, regulatory, and commercial milestones were fully constrained. During the year ended December 31, 2016, the Company received \$10,000 from NHS in connection with the initiation of the Phase 1b study for SER-262 in CDI. During the year ended December 31, 2017, the Company received \$20,000 from NHS in connection with the initiation of the Phase 3 study for SER-109. During the year ended December 31, 2018, the Company received \$40,000 from NHS in connection with the initiation of the Phase 2b study for SER-287. In the third quarter of 2020, the Company increased the transaction price by \$10,000 which represents the milestone payment the Company is entitled to receive from NHS for initiating the SER-301 Phase 1b study. The Company estimated the \$10,000 of variable consideration by using the most likely amount method which best predicts the amount of consideration to which the Company will be entitled. The Company included the \$10,000 of variable consideration in the transaction price because it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. This resulted in \$4,565 of cumulative catch-up revenue in the three and nine months ended September 30, 2020, which was primarily offset by the Company’s updated estimate of the future costs that would be incurred from on-going research and development services to complete its performance obligation under the License Agreement that is recognized over time using an input method. The transaction price as of September 30, 2020 was approximately \$200,000.

During the three and nine months ended September 30, 2020 and 2019, using the cost-to-cost method, which best depicts the transfer of control to the customer, the Company recognized \$80, \$10,728, \$4,840 and \$21,909 of Collaboration revenue – related party, respectively.

As of September 30, 2020 and December 31, 2019, there was \$99,343 and \$110,071, respectively, of deferred revenue related to the unsatisfied portion of the performance obligation under the License Agreement. As of September 30, 2020, the deferred revenue is classified as current or non-current in the condensed consolidated balance sheets based on the Company’s estimate of revenue that will be recognized within the next 12 months, which is determined by the cost-to-cost method which measures the extent of progress towards completion based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the performance obligation. All costs associated with the License Agreement are recorded in research and development expense in the condensed consolidated statements of operations and comprehensive loss.

### ***AstraZeneca Research Collaboration and Option Agreement***

#### *Summary of the Agreement*

In March 2019, the Company entered into a Research Collaboration and Option Agreement (the “Research Agreement”) with MedImmune, LLC, a wholly owned subsidiary of AstraZeneca Inc. (“AstraZeneca”), to advance the mechanistic understanding of the microbiome in augmenting the efficacy of cancer immunotherapy. Under the Research Agreement, the Company and AstraZeneca will conduct certain research and development activities as set forth on a research plan focused on the role of the microbiome in certain cancers and cancer immunotherapies, including furthering the research program for SER-401, in combination with AstraZeneca compounds targeting various cancers.

Pursuant to the Research Agreement, the Company agreed not to conduct research or development on any microbiome products specifically designed by the Company during the term of the Research Agreement for the treatment of cancer (“Microbiome Oncology Products”), with or on behalf of any third party without the prior approval of the joint steering committee for the Research Agreement for at least three years after the effective date (the “Exclusivity Period”). Additionally, AstraZeneca will pay to the Company a total of \$20,000 in three equal installments, the first of which the Company received in April 2019, the second of which the Company received in December 2019, and the third of which becomes due on January 4, 2021. Such payments are payable even if the Research Agreement is terminated in accordance with its terms, unless the Research Agreement is terminated by AstraZeneca for the Company’s uncured material breach. Additionally, AstraZeneca will bear its costs of conducting activities under the research plan and will reimburse the Company for all activities performed under the research plan based on actual full-time employee (“FTE”) time and certain third-party costs incurred by the Company in connection therewith.

Under the Research Agreement, the Company granted to AstraZeneca an exclusive option to negotiate a worldwide, sublicensable exclusive license under relevant intellectual property rights controlled by the Company to exploit Microbiome Oncology Products for the treatment of cancer. Additionally, the Company granted to AstraZeneca an additional exclusive option to obtain a worldwide, sublicensable, license under certain intellectual property rights arising out of the Agreement or coming into the control of the Company during the term of the Agreement, to exploit AstraZeneca’s oncology and other assets which are the subject of the research plan. AstraZeneca may exercise each option at any point prior to 90 days after the end of the Exclusivity Period (the “Option Exercise Period”) by delivering an option exercise notice to the Company. If AstraZeneca exercises an option during the Option Exercise Period, the parties will enter into exclusive, good faith negotiations for a period of six months (the “Negotiation Period”) regarding the terms of the definitive license agreement contemplated by such option. If no definitive agreement is reached during the Negotiation Period, subject to certain other terms and conditions applicable for a one (1) year period, the Company is free to license, further develop or otherwise exploit its assets that were the subject of the option without further obligation to AstraZeneca.

The term of the Research Agreement continues in effect until the Research Agreement is terminated by the parties in accordance with its terms by mutual written agreement. Either party may terminate the Research Agreement for the other party’s uncured material breach or bankruptcy or insolvency-related events. AstraZeneca may terminate the Research Agreement for convenience.

#### *Accounting Analysis*

The Company assessed the Research Agreement in accordance with ASC 606 and concluded that AstraZeneca is a customer. The Company identified the following promises under the contract: (i) a research license, (ii) an obligation to perform research and development services, and (iii) participating on a joint steering committee. The Company assessed the promised goods and services to determine if they are distinct. Based on this assessment, the Company determined that AstraZeneca cannot benefit from the promised goods and services separately from the others as they are highly interrelated and therefore not distinct. Accordingly, the promised goods and services represent one combined performance obligation and the entire transaction price will be allocated to that single combined performance obligation.

Each exclusive option granted to AstraZeneca provides AstraZeneca with the right to negotiate a license agreement in the future at fair value. Therefore, the Company concluded that each option does not constitute a performance obligation at inception and has been excluded from the initial allocation since each option represents a separate buying decision at market rates, rather than a material right in the contract.

At contract inception, the Company determined that the transaction price is comprised of: (i) the \$20,000 fee, which represents fixed consideration, and (ii) the estimated reimbursement of research and development costs incurred, which represents variable consideration. The Company included the estimated reimbursement of research and development costs, approximately \$13,900, in the transaction price at the inception of the arrangement because the Company is required to perform research and development services and the contract requires AstraZeneca to reimburse the Company for costs incurred. Also, since the related revenue would be recognized only as the costs are incurred, and the contract precludes the joint steering committee from changing the research plan without mutual agreement, the Company determined it is not probable that a significant reversal of cumulative revenue would occur.

The Company determined that revenue under the Research Agreement should be recognized over time as AstraZeneca simultaneously receives the benefit from the Company as the Company performs under the single performance obligation over time. The Company will recognize revenue for the single performance obligation using a cost-to-cost input method as the Company has concluded it best depicts the research and joint steering committee participation services performed prior to AstraZeneca's ability to negotiate a license. Under this method, the transaction price is recognized over the contract's entire performance period, using costs incurred relative to total estimated costs to determine the extent of progress towards completion.

In April 2020, preclinical research activities contemplated under the original research plan, in connection with the Research Agreement, were curtailed. The Company and AstraZeneca are in discussions regarding the future scope of translational and clinical activities to be performed by the Company under the research plan. The Company did not perform, or incur costs, under its single performance obligation this quarter. Therefore, no revenue was recognized under the Research Agreement for the three months ended September 30, 2020.

For the three and nine months ended September 30, 2020 and 2019 the Company recognized collaboration revenue of \$0, \$2,016, \$2,106 and \$4,183, respectively, based on the measured progress under the Research Agreement. The transaction price as of September 30, 2020 was approximately \$33,900.

As of September 30, 2020, there was \$8,479 of deferred revenue associated with the Research Agreement, with \$6,784 presented as current and \$1,695 as non-current in the condensed consolidated balance sheets based on the Company's estimate of revenue that will be recognized within the next 12 months. All costs associated with the Research Agreement are recorded in research and development expense in the condensed consolidated statements of operations and comprehensive loss.

#### **Contract Balances from Contracts with Customers**

The following table presents changes in the Company's contract liabilities during the nine months ended September 30, 2020 and 2019 (in thousands):

	Balance as of December 31, 2019	Additions	Deductions	Balance as of September 30, 2020
<b>Nine months ended September 30, 2020</b>				
Contract liabilities:				
Deferred revenue - related party	\$ 110,071	—	(10,728)	\$ 99,343
Deferred revenue	\$ 9,668	827	(2,016)	\$ 8,479
<b>Nine months ended September 30, 2019</b>				
Contract liabilities:				
Deferred revenue - related party	\$ 137,259	—	(21,909)	\$ 115,350
Deferred revenue	\$ —	8,383	(4,183)	\$ 4,200

During the three and nine months ended September 30, 2020 and 2019 the Company recognized the following revenues as a result of changes in the contract liabilities balances in the respective periods (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
<b>Revenue recognized in the period from:</b>				
Amounts included in the contract liability at the beginning of the period	\$ —	\$ 6,081	\$ 11,837	\$ 21,909

When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded. Revenue is recognized from the contract liability over time using the cost-to-cost method.

## 11. Commitments and Contingencies

### *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, 2020 or December 31, 2019.

### *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 would 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, 2020 or December 31, 2019.

## 12. Income Taxes

The Company did not provide for any income taxes for the three and nine months ended September 30, 2020 and 2019.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of September 30, 2020 and December 31, 2019. Management reevaluates the positive and negative evidence at each reporting period.

As of September 30, 2020 and December 31, 2019, the Company had no accrued interest or tax penalties recorded. The Company files income tax returns in the United States and various state jurisdictions. The Company is no longer subject to U.S. federal income tax examinations by tax authorities for years before 2012. However, to the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent it is utilized in a future period. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The Company is currently under examination by the Internal Revenue Service ("IRS") for the period ended December 31, 2018.

### **13. Related Party Transactions**

As described in Note 10, in January 2016 the Company entered into the License Agreement with NHS for the development and commercialization of certain product candidates in development for the treatment and management of CDI and IBD, including UC and Crohn's disease. NHS is a related party since NHS is an affiliate of Nestlé Health Science, one of the Company's significant stockholders. During the three and nine months ended September 30, 2020 and 2019, the Company recognized \$80, \$10,728, \$4,840 and \$21,909 of related party revenue associated with the License Agreement, respectively. As of September 30, 2020 and December 31, 2019 there was \$99,343 and \$110,071 of deferred revenue related to the License Agreement, which is classified as current or non-current in the condensed consolidated balance sheets. The Company has made no payments to NHS during the three and nine months ended September 30, 2020 and 2019. There is no amount due from NHS as of September 30, 2020.

Additionally, on August 12, 2020, the Company entered into the Securities Purchase Agreement with Nestlé for the sale of 959,002 shares of its common stock at a purchase price of \$20.855 per share (the "concurrent placement"). The Company received aggregate net proceeds from the concurrent placement of approximately \$19,900 after deducting offering expenses payable by the Company.

In July 2019, the Company entered into a sublease agreement with Flagship Pioneering, one of the Company's significant stockholders, to sublease a portion of its office and laboratory space in Cambridge, Massachusetts. The term of the sublease agreement commenced in July 2019 and ends on the last day of the 24<sup>th</sup> calendar month following commencement, with no option to extend. Under this agreement, the Company recorded other income of \$458 and \$1,357 during the three and nine months ended September 30, 2020, respectively. The Company received cash payments of \$458 and \$1,357 during the three and nine months ended September 30, 2020, respectively.

## 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 financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2020, or the 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.

### Overview

We are a microbiome therapeutics company developing a novel class of live biotherapeutic drugs, which are consortia of microbes designed to treat disease by modulating the microbiome to repair the function of a disease susceptible microbiome to a non-disease state. We have an advanced drug candidate pipeline with late-stage clinical assets and a differentiated microbiome therapeutics drug discovery and development platform including good manufacturing processes, or GMP, capabilities for this novel drug modality. SER-109 is designed to reduce recurrences of *Clostridioides difficile* infection (formerly *Clostridium difficile* infection), or CDI, a debilitating infection of the colon, in patients who have received antibiotic therapy for recurrent CDI by treating the dysbiosis of the colonic microbiome. As described in further detail below, in August 2020, we reported positive topline results from the pivotal Phase 3 ECOSPOR III study evaluating SER-109 for recurrent CDI. If approved by the U.S. Food and Drug Administration, or FDA, SER-109 could be a first-in-field oral microbiome drug. SER-287 and SER-301 are being developed to treat ulcerative colitis, or UC. In addition, using our microbiome therapeutics platform, we are developing SER-401, a microbiome therapeutic candidate for use with checkpoint inhibitors in patients with metastatic melanoma and SER-155 to prevent mortality due to gastrointestinal infections, bacteremia and graft versus host disease (“GvHD”) in immunocompromised patients, including in patients receiving allogeneic hematopoietic stem cell transplantation (allo-HSCT). Supporting our R&D efforts are our deep capabilities related to microbiome therapeutic drug discovery, manufacturing, quality, and clinical development. We believe that these capabilities provide us with important competitive advantages related to the advancement of this novel treatment modality.

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

All of our product candidates other than SER-109, SER-287, SER-301, SER-401, and SER-155 are still in pre-clinical development or early stage discovery. Our ability to generate product revenue sufficient 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 was \$70.9 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of \$530.5 million and cash, cash equivalents and short- and long-term investments totaling \$320.3 million. Based on our current plans and forecasted expenses, we believe that our existing cash, cash equivalents and investments as of September 30, 2020 will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12-months from issuance of our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

In August 2020, we completed an underwritten public offering in which we sold 10,500,000 shares of our common stock at a public offering price of \$21.50 per share. In addition, we granted the underwriters a 30-day option to purchase up to an additional 1,575,000 shares of our common stock at the public offering price, less underwriting discounts and commissions, which the underwriters exercised in full. We received aggregate net proceeds from the offering of approximately \$243.7 million after deducting underwriting discounts and commissions and offering expenses payable by us.

Also in August 2020, we entered into a Securities Purchase Agreement with Nestlé for the sale of 959,002 shares of our common stock at a purchase price of \$20.855 per share, or the “concurrent placement.” We received aggregate net proceeds from the concurrent placement of approximately \$19.9 million after deducting offering expenses payable by us. See “—Liquidity and Capital Resources.”

### Impact of Novel Coronavirus

We are monitoring the global outbreak and spread of the novel strain of coronavirus, or COVID-19, and have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address the COVID-19 pandemic. The spread of COVID-19 has caused us to modify our business practices, including implementing a work from home policy for all employees who are able to perform their duties remotely and restricting all nonessential travel, and we expect to continue to take actions as may be required or recommended by government authorities or as we

determine are in the best interests of our employees, and other business partners in light of COVID-19. Given the fluidity of the COVID-19 pandemic however, we do not yet know the full extent of the potential impact of COVID-19 on our business operations. We will continue to closely monitor the impact of the COVID-19 pandemic on our operations and ongoing clinical development activity. For additional information related to the potential impact of COVID-19 on our business, please read Part II-Item 1A, "Risk Factors" of this Quarterly Report on Form 10-Q.

### **SER-109**

SER-109 is an oral, biologically-derived, purified bacterial spore-based microbiome therapeutic candidate consisting of bacterial species purified from healthy donor stool. Our SER-109 manufacturing process includes inactivation and clearance steps designed to eliminate potential pathogens. SER-109 is designed to prevent further recurrences of CDI in patients with a history of multiple infections by restructuring the dysbiotic microbiome to a state that resists *C. difficile* colonization and growth.

In August 2020, we reported positive topline results from the pivotal Phase 3 ECOSPOR III study evaluating SER-109 for recurrent CDI. The study showed that SER-109 administration resulted in a highly statistically significant absolute decrease of 30.2% in the proportion of patients who experienced a recurrence in CDI within eight weeks of administration versus placebo, the study's primary endpoint, and which remained consistent at 12-weeks end point with a 31.1% absolute decrease. At eight weeks of treatment, 11.1% of patients administered SER-109 experienced a CDI recurrence, versus 41.3% of placebo patients. The study results were equally compelling when characterized by the alternative metric of sustained clinical response, where 88.9% of patients in the SER-109 arm achieved this objective at eight weeks.

The study's efficacy results exceeded the statistical threshold previously provided in consultation with the FDA that could allow this single clinical study to fulfill efficacy requirements for a biological license application, or BLA. The SER-109 safety results observed to-date were favorable, with an adverse event profile comparable to placebo. We are actively enrolling patients in our SER-109 open-label study, which also admits patients with a single recurrence of CDI, to expand the safety database to meet the FDA guidance of at least 300 patients.

SER-109, if approved, is intended to treat individuals with recurrent CDI, a patient population which includes approximately 170,000 individuals per year in the United States. We completed enrollment with 182 patients of 188 intended subjects with multiply recurrent CDI in ECOSPOR III. All patients who entered ECOSPOR III must have tested positive for *C. difficile* toxin, as currently recommended by the Infectious Diseases Society of America guidelines (McDonald Clin Infect Dis 2018). This inclusion criterion was implemented in an effort to ensure enrollment of only patients with active infection rather than simple colonization. The study was designed to evaluate patients for 24 weeks with the primary endpoint of comparing the *C. difficile* recurrence rate in subjects who receive SER-109 versus placebo at up to eight weeks after dosing.

### **SER-287**

SER-287 is an oral, biologically-derived purified microbiome therapeutic candidate designed to normalize the gastrointestinal microbiome of individuals with UC. In December 2018, we commenced a three-arm placebo-controlled Phase 2b clinical trial that was designed to evaluate SER-287 in approximately 201 patients with mild-to-moderate UC. Two groups of patients are receiving different doses of SER-287, both following pretreatment with a short course of oral vancomycin. A third study arm will receive placebo. The study's primary endpoint will evaluate clinical remission measured after 10 weeks of SER-287 administration. Patients then enter a 2-week exploratory maintenance follow-up period. Endoscopic improvement will be measured as a secondary efficacy measure. Based on feedback from the FDA, if the data from this trial is positive, we expect that the Phase 2b clinical trial could be one of two pivotal trials to enable a BLA to be submitted for SER-287 for the treatment of UC. The SER-287 Phase 2b study is over 75% enrolled based on the 201-patient target study size. SER-287 development activity has been adversely impacted by the COVID-19 pandemic and by multiple clinical sites halting non-essential procedures, including endoscopies. In recent weeks, we have observed an increase in ECO-RESET clinical site activity, the availability of endoscopies, and in the volume of clinical study subject screening. Seres is evaluating enrollment mitigation strategies and possible trial design modifications with the goal of obtaining a high-quality, clinically meaningful dataset. We plan to engage FDA in discussions regarding any potential trial modifications.

There are approximately 700,000 UC patients in the United States and fewer than one-third of patients on current therapies achieve remission. Approved treatments are often inadequate to control disease activity and are often associated with significant side effects, including immunosuppression. We believe that SER-287 may address underlying drivers of inflammation in UC and, based on the favorable tolerability profile observed in our clinical trials of SER-287, has the potential to be developed as both a foundational monotherapy, as well as a combination therapy with other UC drugs. SER-287 has been granted Fast Track Designation by the FDA for the induction and maintenance of clinical remission in adult subjects with active mild-to-moderate UC. SER-287 has been designated an Orphan Drug for pediatric UC by the FDA.

### **SER-301**

We are also advancing our next generation, rationally-designed, fermented microbiome drug discovery and development capabilities, focusing on advancing SER-301, a therapeutic candidate for UC. We have nominated the SER-301 lead candidate. SER-301 is a consortia of bacteria designed using our reverse translational discovery platform that incorporates analysis of microbiome biomarkers from human clinical data and preclinical assessments using human cell-based assays and *in vitro/ex vivo* and *in vivo* disease models. SER-301 is designed to reduce induction of pro-inflammatory activity, improve epithelial barrier integrity and TNF- $\alpha$  driven inflammation in IECs, and modulate UC-relevant anti-inflammatory, innate and adaptive immune pathways. SER-301 is being produced by our advanced fermentation, formulation and delivery platforms. It includes strains delivered in spore form, as well as strains fermented in non-spore (vegetative) form and delivered using enterically-protected technology designed to release in the colon.

We have initiated clinical development activities for SER-301, and in November 2020 we enrolled our first patient in the SER-301 Phase 1b study. This initial clinical study of SER-301 will be conducted in Australia and New Zealand. As a result of enrolling the first patient in the clinical study, we are entitled to receive a \$10.0 million milestone payment under our collaboration agreement with Nestec Ltd.

### **SER-401**

SER-401 is an oral biologically-derived purified microbiome therapeutic candidate comprising a bacterial signature similar to that observed in checkpoint inhibitor immunotherapy responders. In March 2019, the first patient was dosed in the Phase 1b clinical study with MD Anderson and PICI, to evaluate SER-401's potential to augment the response of anti-PD-1 checkpoint inhibitor therapy. The study is designed to enroll 30 patients with metastatic melanoma who are being treated with nivolumab, an anti-PD-1 therapy. Patients are randomized at a 2-to-1 ratio to either SER-401 or placebo. The study's primary endpoints are to evaluate safety and tolerability. Its secondary endpoints are to evaluate the correlation of microbiome biomarkers of response to various clinical and immunological outcome measures.

Seres continues to monitor the impact of the COVID-19 pandemic on company operations and ongoing clinical development activity, including on the SER-401 Phase 1b study in metastatic melanoma. Mitigation activities to minimize COVID-19-related operation disruptions are ongoing, however, given the severity and evolving nature of the situation, the timing of the SER-401 Phase 1b clinical readout is uncertain.

### **SER-155**

We have nominated the SER-155 lead candidate, a rationally-designed, fermented microbiome drug and are advancing the candidate into clinical development. 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-HSCT patients with decreased diversity of commensal microbes are significantly more likely to die due to infection and/or lethal graft versus host disease, or GvHD. SER-155 is consortia of bacteria designed using our reverse translational discovery platform to prevent mortality due to gastrointestinal infections, bacteremia and GvHD in immunocompromised patients, including in patients receiving allogeneic hematopoietic stem cell transplantation (allo-HSCT) or solid organ transplants. SER-155 lead candidate is designed to decrease infection and translocation of antibiotic resistant bacteria in the gastrointestinal tract and modulate host immune responses to decrease GvHD. In November 2017, we were awarded a highly competitive grant from CARB-X to support continued preclinical research and early development work for SER-155. In 2019, Seres was awarded additional funding from CARB-X to support clinical development of SER-155, including support through IND filing and Phase 1b evaluation. The 2019 CARB-X grant provides us with an additional \$4.8 million of funding for research, manufacture, and IND application, with potential for an additional \$7.0 million for Phase 1b development, upon completion of milestones.

While we plan to focus our investment on our highest priority clinical programs in the near-term, our expenses may increase substantially in connection with our ongoing and planned activities, particularly as we:

- complete the clinical development and prepare for commercialization of SER-109 for the prevention of recurrent CDI;
- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC;
- continue the clinical development of SER-301 for the treatment of UC;
- continue the clinical development of SER-401 in our Phase 1b clinical trial for use with checkpoint inhibitors in patients with metastatic melanoma;
- initiate clinical development of SER-155 for the prevention of mortality due to GvHD in immunocompromised patients, including in patients receiving allo-HSCT;
- make strategic investments in manufacturing capabilities;



- make strategic investments in our research discovery and development platforms and capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- potentially establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- perform our obligations under our agreements with our 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.

In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, 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 public or private equity or debt financings or other sources, which may include collaborations with third parties. 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 the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. See "Risk Factors—Risks Related to Our Operations—The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition" in Part II, Item 1A of this Quarterly Report on Form 10-Q. Our inability to raise capital 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.

## **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. For example, our portfolio includes an option to license foundational intellectual property related to the use of bacteria in combination with checkpoint inhibitors from MD Anderson. 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-109 (*C. difficile*) and SER-287 (ulcerative colitis) extend through 2033. We plan on continuing to broaden our patent portfolio. Currently, we have 21 active patent application families, which includes 15 nationalized applications and 1 pending US provisional application. To date, we have obtained 13 issued U.S. patents.

### ***Regulatory Exclusivity***

If we obtain marketing approval for any of our product candidates, we expect to receive marketing exclusivity against biosimilar products. For a new biological composition approved by the FDA, a 12-year period of exclusivity in the United States may be obtained. In Europe, the European Medicines Agency awards 10 years of exclusivity for new molecular entities.

## **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.

## 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, which include:

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research, pre-clinical activities and clinical trials on our behalf as well as contract manufacturing organizations that manufacture drug products for use in our pre-clinical 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 pre-clinical study and clinical trial materials;
- costs related to compliance with regulatory requirements; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

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 financial statements as prepaid or accrued research and development expenses. All costs associated with the collaboration and license agreement, or the License Agreement, with Nestec Ltd., or NHS, and the Research Agreement are recorded in research and development expense in the condensed consolidated statements of operations and comprehensive loss.

Our primary focus of research and development since inception has been on our microbiome therapeutics 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 pre-clinical 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 and, as such, are classified as costs of our microbiome therapeutics platform research, along with external costs directly related to our microbiome therapeutics platform.

The table below summarizes our research and development expenses incurred on our platform and by product development program for those that have begun clinical development.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Microbiome therapeutics platforms	\$ 12,456	\$ 10,861	\$ 36,744	\$ 37,684
SER-109	5,668	2,829	12,199	7,690
SER-287	3,870	4,430	13,109	12,105
Early stage programs	1,867	197	3,651	1,630
Total research and development expenses	<u>\$ 23,861</u>	<u>\$ 18,317</u>	<u>\$ 65,703</u>	<u>\$ 59,109</u>

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 expect that our research and development expenses will continue to increase in the foreseeable future as we conduct our ECOSPOR III Phase 3 clinical study of SER-109, advance the clinical development of SER-287, continue to discover and develop additional product candidates, including SER-301, SER-401 and SER-155 and pursue later stages of clinical development of our product candidates.

### *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, corporate 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 and other operating costs.

Our general and administrative expenses may increase in the future as we increase our headcount to support the potential growth in our research and development activities and the potential commercialization of our product candidates. We also may 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 Securities and Exchange Commission, or the SEC, director and officer insurance costs and investor and public relations costs.

### *Restructuring*

In February 2019, we implemented corporate changes to focus our resources on advancing our clinical-stage therapeutic candidates. As a result, we are concentrating on obtaining results from the ongoing SER-109 Phase 3 study for recurrent CDI, completing our SER-287 Phase 2b study in mild-to-moderate UC patients, advancing the SER-401 Phase 1b study in collaboration with the PICI and MD Anderson to evaluate augmenting checkpoint inhibitor response in patients with metastatic melanoma, and advancing SER-301 into clinical development. In connection with the prioritization of these therapeutics candidates, we made changes to our management team and reduced headcount by approximately 30 percent.

### ***Other Income (Expense), Net***

#### *Interest Income (Expense), Net*

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

Interest expense consists of interest incurred under our loan and security agreement with Hercules.

#### *Other Income*

Other income primarily consists of sublease income.

### ***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, 2020 or 2019.

### **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, 2019, filed with the SEC on March 2, 2020, 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, 2020.

## Results of Operations

### Comparison of Three Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Change
	2020	2019	
(in thousands)			
<b>Revenue:</b>			
Collaboration revenue - related party	\$ 80	\$ 4,840	\$ (4,760)
Grant revenue	1,337	85	1,252
Collaboration revenue	—	2,106	(2,106)
<b>Total revenue</b>	<b>1,417</b>	<b>7,031</b>	<b>(5,614)</b>
<b>Operating expenses:</b>			
Research and development	23,861	18,317	5,544
General and administrative	7,551	5,897	1,654
Restructuring expenses	—	—	—
<b>Total operating expenses</b>	<b>31,412</b>	<b>24,214</b>	<b>7,198</b>
<b>Loss from operations</b>	<b>(29,995)</b>	<b>(17,183)</b>	<b>(12,812)</b>
<b>Other (expense) income:</b>			
Interest income	100	335	(235)
Interest expense	(730)	—	(730)
Other income	345	439	(94)
<b>Total other (expense) income, net</b>	<b>(285)</b>	<b>774</b>	<b>(1,059)</b>
<b>Net loss</b>	<b>\$ (30,280)</b>	<b>\$ (16,409)</b>	<b>\$ (13,871)</b>

#### Revenue

Total revenue was \$1.4 million and \$7.0 million for the three months ended September 30, 2020 and 2019, respectively. The revenue for the three months ended September 30, 2020 relates primarily to \$1.3 million of grant revenue and \$0.1 million recognized under our license and collaborative agreement with Nestec Ltd., or the License Agreement. The revenue for the three months ended September 30, 2019 principally relates to the recognition of amounts received under the License Agreement of \$4.8 million and \$2.1 million associated with our research collaboration and option agreement with MedImmune, LLC, a wholly owned subsidiary of AstraZeneca Inc., or the Research Agreement. The decrease of \$5.6 million is mainly attributed to a \$4.8 million decrease in the License Agreement revenue, which is primarily a result of an increase in our total estimated costs expected to complete our single performance obligation driven by our active enrollment of patients in our open-label study for SER-109 in order to expand the safety database to meet the FDA guidance of at least 300 patients and SER-287 clinical development activity being adversely impacted by the COVID-19 pandemic. This decrease was partially off-set by cumulative catch-up revenue of \$4.6 million associated with the increase of \$10.0 million to the transaction price related to the milestone payment we are entitled to receive from NHS for initiating the SER-301 Phase 1b study. Additionally, there was a \$2.1 million decrease in the revenue associated with the Research Agreement due to the curtailment of preclinical research activities contemplated under the original research plan in the second quarter of 2020. This is off-set by an increase of \$1.3 million in grant revenue.

#### Research and Development Expenses

	Three Months Ended September 30,		Change
	2020	2019	
(in thousands)			
Microbiome therapeutics platforms	\$ 12,456	\$ 10,861	\$ 1,595
SER-109	5,668	2,829	2,839
SER-287	3,870	4,430	(560)
Early stage programs	1,867	197	1,670
<b>Total research and development expenses</b>	<b>\$ 23,861</b>	<b>\$ 18,317</b>	<b>\$ 5,544</b>

Research and development expenses were \$23.9 million for the three months ended September 30, 2020, compared to \$18.3 million for the three months ended September 30, 2019. The increase of \$5.5 million was due primarily to the following:

- an increase of \$1.6 million in research expenses related to our microbiome therapeutics platform due primarily to employee related costs;
- an increase of \$2.8 million in expenses related to our SER-109 program due primarily to an increase in sequencing work of \$1.1 million, an increase in employee related costs of \$0.8 million, an increase in contract manufacturing of \$0.7 million, and an increase in facility expenses of \$0.2 million;
- a decrease of \$0.6 million in expenses for our SER-287 program due primarily to a decrease in contract manufacturing of \$0.8 million, a decrease in clinical trial consulting expense of \$0.3 million, and partially offset by an increase in employee related costs of \$0.5 million; and
- an increase of \$1.7 million in expenses for our early stage programs due primarily to an increase in clinical trials consulting expense of \$1.4 million and an increase in facility expenses of \$0.2 million.

#### *General and Administrative Expenses*

	<u>Three Months Ended September 30,</u>		<u>Change</u>
	<u>2020</u>	<u>2019</u>	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 2,659	\$ 2,103	\$ 556
Professional fees	3,354	2,406	948
Facility-related and other	1,538	1,388	150
Total general and administrative expenses	<u>\$ 7,551</u>	<u>\$ 5,897</u>	<u>\$ 1,654</u>

General and administrative expenses were \$7.6 million for the three months ended September 30, 2020, compared to \$5.9 million for the three months ended September 30, 2019. The increase of \$1.7 million was primarily due to the following:

- an increase in personnel related costs of \$0.6 million primarily related to an increase in salaries and related payroll taxes;
- an increase in professional fees of \$0.9 million is primarily due to an increase in consulting fees; and
- an increase in facility-related and other costs of \$0.2 million primarily due to an increase in IT-related expenses

#### *Other Income (Expense), Net*

Other income (expense), net for the three months ended September 30, 2020 and 2019 was \$(0.3) million and \$0.8 million, respectively. The decrease is primarily due to an increase in interest expense of \$0.7 million and a decrease of interest income of \$0.2 million.

## Comparison of the Nine Months Ended September 30, 2020 and September 30, 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30,		Change
	2020	2019	
	(in thousands)		
<b>Revenue:</b>			
Collaboration revenue - related party	\$ 10,728	\$ 21,909	\$ (11,181)
Grant revenue	2,907	791	2,116
Collaboration revenue	2,016	4,183	(2,167)
Total revenue	15,651	26,883	(11,232)
<b>Operating expenses:</b>			
Research and development	65,703	59,109	6,594
General and administrative	20,180	18,966	1,214
Restructuring expenses	—	1,492	(1,492)
Total operating expenses	85,883	79,567	6,316
Loss from operations	(70,232)	(52,684)	(17,548)
<b>Other income (expense):</b>			
Interest income	333	744	(411)
Interest expense	(2,165)	—	(2,165)
Other income	1,189	439	750
Total other income (expense), net	(643)	1,183	(1,826)
Net loss	\$ (70,875)	\$ (51,501)	\$ (19,374)

### Revenue

Total revenue was \$15.7 million and \$26.9 million for the nine months ended September 30, 2020 and 2019, respectively. The revenue for the nine months ended September 30, 2020 relates to \$10.7 million recognized under the License Agreement, \$2.9 million for grant revenue and \$2.0 million recognized under the Research Agreement. The revenue for the nine months ended September 30, 2019 principally relates to the recognition of amounts received under the License Agreement. The decrease of \$11.2 million is mainly attributed to a \$11.2 million decrease in the License Agreement revenue, which is primarily a result of an increase in our total estimated costs expected to complete our single performance obligation driven by our active enrollment of patients in our open-label study for SER-109 in order to expand the safety database to meet the FDA guidance of at least 300 patients and SER-287 clinical development activity being adversely impacted by the COVID-19 pandemic. This decrease was partially off-set by cumulative catch-up revenue of \$4.6 million associated with the increase of \$10.0 million to the transaction price related to the milestone payment we are entitled to receive from NHS for initiating the SER-301 Phase 1b study.

### Research and Development Expenses

	Nine Months Ended September 30,		Change
	2020	2019	
	(in thousands)		
Microbiome therapeutics platforms	\$ 36,744	\$ 37,684	\$ (940)
SER-109	12,199	7,690	4,509
SER-287	13,109	12,105	1,004
Early stage programs	3,651	1,630	2,021
Total research and development expenses	\$ 65,703	\$ 59,109	\$ 6,594

Research and development expenses were \$65.7 million for the nine months ended September 30, 2020, compared to \$59.1 million for the nine months ended September 30, 2019. The increase of \$6.6 million was due primarily to the following:

- a decrease of \$0.9 million in research expenses related to our microbiome therapeutics platform, due primarily to a decrease in facility expenses of \$1.4 million and partially offset by an increase in employee related costs of \$0.5 million;
- an increase of \$4.5 million in expenses related to our SER-109 program due primarily to an increase in employee related costs of \$1.8 million, an increase in sequencing costs of \$1.1 million, an increase in contract manufacturing of \$0.8 million, and an increase in facility expenses of \$0.5 million;

- an increase of \$1.0 million in expenses for our SER-287 program due primarily to an increase in lab services and maintenance of \$1.3 million, an increase in clinical trial consulting expense of \$1.2 million, an increase in employee related costs of \$0.5 million, an increase in sequencing costs of \$0.5 million, and partially offset by a decrease in contract manufacturing of \$2.4 million; and
- an increase of \$2.0 million in expenses for our early stage programs due primarily to an increase clinical trials consulting expense of \$1.8 million, and an increase in lab service and maintenance of \$0.2 million.

#### General and Administrative Expenses

	Nine Months Ended September 30,		Change
	2020	2019	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 7,304	\$ 7,486	\$ (182)
Professional fees	8,676	6,883	1,793
Facility-related and other	4,200	4,597	(397)
Total general and administrative expenses	<u>\$ 20,180</u>	<u>\$ 18,966</u>	<u>\$ 1,214</u>

General and administrative expenses were \$20.2 million for the nine months ended September 30, 2020 compared to \$19.0 million for the nine months ended September 30, 2019. The increase of \$1.2 million was primarily due to the following:

- a decrease in personnel related costs of \$0.2 million primarily related to a decrease in salary costs;
- an increase in professional fees of \$1.8 million primarily due to an increase in consulting; and
- a decrease in facility-related and other costs of \$0.4 million primarily due to a decrease in IT-related expenses.

#### Restructuring

There were no restructuring charges for the nine months ended September 30, 2020. There were \$1.5 million of restructuring charges for the nine months ended September 30, 2019 related to the corporate restructuring discussed above.

#### Other Income (Expense), Net

Other income (expense), net for the nine months ended September 30, 2020 and 2019 was \$(0.6) million and \$1.2 million, respectively. The decrease is primarily due to an increase in interest expense of \$2.2 million and partially offset by an increase in other income of \$0.8 million primarily related to our sublease.

### Liquidity and Capital Resources

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

In August 2020, we completed an underwritten public offering in which we sold 10,500,000 shares of the Company's common stock at a public offering price of \$21.50 per share. In addition, we granted the underwriters a 30-day option to purchase up to an additional 1,575,000 shares of its common stock at the public offering price, less underwriting discounts and commissions, which the underwriters exercised in full. We received aggregate net proceeds from the offering of approximately \$243.7 million after deducting underwriting discounts and commissions and offering expenses payable by us.

In August 2020, we entered into a Securities Purchase Agreement with Nestlé for the sale of 959,002 shares of our common stock at a purchase price of \$20.855 per share (the "concurrent placement"). We received aggregate net proceeds from the concurrent placement of approximately \$19.9 million after deducting offering expenses payable by us.

In November 2019, we entered into a sales agreement, the 2019 Sales Agreement, with Cowen to sell shares of our common stock with aggregate gross sales proceeds of up to \$25.0 million, from time to time, through an ATM under which Cowen acts as sales agent. In March 2020, in connection with filing an updated registration statement on Form S-3 (File No. 333-237033), we entered into a new sales agreement, the 2020 Sales Agreement, with Cowen on substantially the same terms as the 2019 Sales Agreement and terminated the 2019 Sales Agreement. From January 1, 2020 to September 30, 2020, we sold approximately 5.8 million shares of common stock under the 2019 Sales Agreement and the 2020 Sales Agreement, as applicable, at an average price of approximately \$4.40 per share, raising aggregate net proceeds of approximately \$24.8 million after deducting an aggregate commission of approximately 3%.

As of September 30, 2020, we had cash, cash equivalents and short- and long-term investments totaling \$320.3 million and an accumulated deficit of \$530.5 million. Based on our current plans and forecasted expenses, we believe that our cash, cash equivalents and investments as of September 30, 2020 will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements for at least the next 12-months from issuance of our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, subject to compliance with the conditions and covenants of our Loan and Security Agreement with Hercules Capital, Inc. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

## **Collaboration Agreements**

### *Agreement with NHS*

In January 2016, we entered into the License Agreement, for the development and commercialization of certain of our product candidates in development for the treatment and management of CDI and IBD, including UC and Crohn's disease. In exchange for the license, NHS agreed to pay us an upfront cash payment of \$120.0 million, which we received in February 2016. NHS has also agreed to pay us tiered royalties, at percentages ranging from the high single digits to high teens, of net sales of certain products based on our microbiome technology that are being developed for the treatment of CDI and IBD, including SER-109, SER-262, SER-287 and SER-301, or collectively, the NHS Collaboration Products in markets outside of the United States and Canada, or the Licensed Territory. We have retained full commercial rights to the NHS Collaboration Products with respect to the United States and Canada, where we plan to build our own commercial organization. We are eligible to receive up to \$285.0 million in development milestone payments, \$375.0 million in regulatory payments and up to an aggregate of \$1.1 billion for the achievement of certain commercial milestones related to the sales of NHS Collaboration Products. The full potential value of the up-front payment and milestone payments payable by NHS is over \$1.9 billion, assuming all products receive regulatory approval and are successfully commercialized. In September 2016, we received a \$10.0 million milestone payment associated with the initiation of the Phase 1b clinical study for SER-262 in CDI. In June 2017, we initiated a Phase 3 clinical study of SER-109 (ECOSPOR III) in patients with multiply recurrent CDI. In July 2017, we recorded revenue of \$20.0 million based on the achievement of this milestone under the License Agreement. In November 2018, we executed a letter agreement with NHS, or the Letter Agreement, modifying certain terms of the License Agreement. Under the Letter Agreement, NHS agreed to pay us the \$20.0 million Phase 3 milestone payment upon commencement of the Phase 2b study for SER-287. In December 2018, we received \$40.0 million in milestone payments in connection with the commencement of the Phase 2b study for SER-287.

For the development of NHS Collaboration Products for IBD under a global development plan, we agreed to pay the costs of clinical trials of such products up to and including Phase 2 clinical trials, and 67% of the costs for Phase 3 and other clinical trials of such products, with NHS bearing the remaining 33% of such costs. The Letter Agreement also provides scenarios under which NHS' reimbursement to us for certain Phase 3 development costs would be reduced or delayed depending on the outcomes of the SER-287 Phase 2b study. For other clinical development of NHS Collaboration Products for IBD, we agreed to pay the costs of such activities to support approval in the United States and Canada, and NHS agreed to bear the cost of such activities to support approval of NHS Collaboration Products in the Licensed Territory.

With respect to development of NHS Collaboration Products for CDI under a global development plan, we agreed to pay all costs of Phase 2 clinical trials for SER-109 and for Phase 3 clinical trials for SER-109. We agreed to bear all costs of conducting any Phase 1 or Phase 2 clinical trials under a global development plan for NHS Collaboration Products other than SER-109 for CDI. We agreed to pay 67% and NHS agreed to pay 33% of other costs of Phase 3 clinical trials conducted for NHS Collaboration Products other than SER-109 for CDI under a global development plan. For other clinical development of NHS Collaboration Products for CDI, we agreed to pay costs of such development activities to support approval in the United States and Canada, and NHS agreed to bear the cost of such activities to support approval of NHS Collaboration Products in the Licensed Territory.

### *Agreement with AstraZeneca*

In March 2019, we entered into the Research Agreement with AstraZeneca. Pursuant to the Research Agreement, we and AstraZeneca agreed to conduct certain pre-clinical and development activities and may conduct certain clinical research with the goal of advancing the mechanistic understanding of the microbiome in augmenting the efficacy of cancer immunotherapy, including potential synergy with AstraZeneca compounds in accordance with a mutually agreed research plan. Pursuant to the Research Agreement, we agreed not to conduct research or development of any microbiome products specifically designed by us during the term of the Research Agreement for the treatment of cancer with or on behalf of any third party without the prior approval of the joint steering committee for the Research Agreement until at least three years after the effective date of the Research Agreement.

AstraZeneca has agreed to bear all costs of conducting its activities under the research plan and to reimburse us for certain costs incurred under the research plan. Additionally, AstraZeneca has agreed to pay to us a total of \$20.0 million in three equal installments, the first of which we received in April 2019, the second of which we received in December 2019, and the third of which will become due on January 4, 2021. Such payments are payable even if the Research Agreement is terminated in accordance with its terms, unless the Research Agreement is terminated by AstraZeneca for our uncured material breach.



We also granted AstraZeneca an exclusive option to negotiate exclusive license rights to certain of our technologies and assets. If AstraZeneca exercises this option, we have agreed to enter into good faith negotiations with them for terms and conditions of such license agreement for a specified time period.

In April 2020, preclinical research activities contemplated under the original research plan, in connection with the Research Agreement, were curtailed. We are in discussions regarding the future scope of translational and clinical activities to be performed by us under the research plan. We did not perform, or incur costs, under the single performance obligation this quarter. Therefore, no revenue was recognized under the Research Agreement for the three months ended September 30, 2020.

## **Indebtedness**

### *Loan and Security Agreement with Hercules*

In October 2019, we entered into a loan and security agreement with Hercules, pursuant to which a term loan in an aggregate principal amount of up to \$50.0 million, or the Term Loan Facility, was available to us in three tranches, subject to certain terms and conditions. We received the first tranche of \$25.0 million upon signing the agreement on October 29, 2019. We did not meet the milestone requirements for the second tranche under the Term Loan Facility, and as such, the additional second tranche amount of up to \$12.5 million is not available for us to borrow. The third tranche, which allows us to borrow an additional \$12.5 million, will be available upon Hercules' approval on or prior to June 30, 2021.

Advances under the Term Loan Facility will bear interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 4.40%, and (ii) 9.65%. We will make interest only payments through December 1, 2021, or extended to June 1, 2022 upon satisfaction of certain milestones, and will then repay the principal balance and interest of the advances in equal monthly installments after the interest only period and continuing through November 1, 2023. We paid Hercules a commitment fee of \$0.4 million at the closing. We may prepay advances under the loan and security agreement with Hercules, in whole or in part, at any time subject to a prepayment charge equal to: (a) 3.0 % of amounts so prepaid, if such prepayment occurs during the first year; (b) 2.0% of the amount so prepaid, if such prepayment occurs during the second year, and (c) 1.0% of the amount so prepaid, if such prepayment occurs after the second year. Upon prepayment or repayment of all or any of the term loans, we will pay (in addition to the prepayment premium) an end of term charge of 4.85% of the aggregate funded amount under the Term Loan Facility.

The Term Loan Facility is secured by substantially all of our assets, other than our intellectual property. We have agreed to not pledge or secure our intellectual property to others.

The Term Loan Facility includes affirmative and negative covenants applicable to us. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on our transferring collateral, making changes to the nature of our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, engaging in transactions with affiliates, creating liens and selling assets, in each case subject to certain exceptions, including, among others, the ability for us to issue up to \$150.0 million in convertible notes and entering into exclusive outbound licenses for our intellectual property. The Term Loan Facility also includes a liquidity covenant that commences either October 31, 2020, or December 31, 2020 based upon our satisfying certain performance milestones. If our market capitalization exceeds \$350.0 million, we do not have to comply with the liquidity covenant if such covenant is required.

The Term Loan Facility also includes events of default, the occurrence and continuance of which provide Hercules with the right to demand immediate repayment of all principal and unpaid interest, and to exercise remedies against us and the collateral. These events of default include, among other things and subject to customary exceptions: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the loan and security agreement with Hercules or other loan documents on a timely basis; (iii) failure to observe certain covenants under the loan and security agreement with Hercules; (v) occurrence of a material adverse effect; (vi) material misrepresentation by us; (vii) occurrence of any default under any other agreement involving material indebtedness; and (viii) certain material money judgments.

On April 16, 2020, we entered into an amendment to the loan and security agreement with Hercules, permitting us to enter into a promissory note under the Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Stability Act. On April 17, 2020 we issued a Promissory Note to Bank of America, NA, pursuant to which we received loan proceeds of \$2.9 million (the "Loan"), however, based on updated guidance related to this program, we decided to repay the full amount of the Loan, and repaid the Loan on May 4, 2020.

As of September 30, 2020 and December 31, 2019, the outstanding principal under the Term Loan Facility was \$25.0 million and \$24.6 million, respectively. For a further description of the Term Loan Facility, see Note 8 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

## Cash Flows

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

	Nine Months Ended September 30,	
	2020	2019
	(in thousands)	
Cash used in operating activities	\$ (75,683)	\$ (62,473)
Cash used in investing activities	(83,556)	(35,171)
Cash provided by financing activities	301,439	61,121
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 142,200</u>	<u>\$ (36,523)</u>

### Operating Activities

During the nine months ended September 30, 2020, operating activities used \$75.7 million of cash, primarily due to a net loss of \$70.9 million and cash used from changes in our operating assets and liabilities of \$17.9 million, partially offset by non-cash charges of \$13.1 million. Net cash used for changes in our operating assets and liabilities during the nine months ended September 30, 2020 consisted of an increase in prepaid expenses and other current assets of \$3.1 million, an increase in accounts receivable of \$1.6 million, a decrease in deferred revenue of \$11.9 million, an increase in accounts payable of \$1.0 million, a decrease in operating lease liabilities of \$3.3 million and an increase in accrued expenses and other current liabilities of \$0.9 million. The increase in prepaid expenses is due to timing of payments to vendors. The increase in accounts receivable is due to our reimbursable costs per our agreements. The decrease in deferred revenue was primarily due to the recognition of collaboration revenue. The increase in accounts payable was due to the timing of payments. The decrease in operating lease liabilities was due to the cash payment of lease obligations.

During the nine months ended September 30, 2019, operating activities used \$62.5 million of cash, primarily due to a net loss of \$51.5 million and cash used from changes in our operating assets and liabilities of \$24.6 million, partially offset by non-cash charges of \$13.6 million. Net cash used for changes in our operating assets and liabilities during the nine months ended September 30, 2019 consisted of a decrease in prepaid expenses and other current assets of \$2.8 million, an increase in accounts receivable of \$1.7 million, a decrease in deferred revenue of \$17.7 million, a decrease in accounts payable of \$1.9 million, a decrease in operating lease liabilities of \$3.2 million, and a decrease in accrued expenses and other current liabilities of \$2.9 million. The decrease in prepaid expenses and other current liabilities is due to amortization. The increase in accounts receivable is primarily due to our reimbursable costs per our agreements. The decrease in deferred revenue was due to the recognition of collaboration revenue. The decrease in accounts payable and accrued expenses and other current liabilities was due to the timing of payments. The decrease in operating lease liabilities was due to the cash payment of lease obligations.

### Investing Activities

During the nine months ended September 30, 2020, net cash used in investing activities was \$83.6 million, consisting maturities of investments of \$42.8 million, partially offset by purchases of investments of \$126.0 million and purchases of property and equipment of \$0.4 million.

During the nine months ended September 30, 2019, net cash used in investing activities was \$35.2 million, consisting of purchases of investments of \$34.4 million and purchases of property and equipment of \$0.8 million.

### Financing Activities

During the nine months ended September 30, 2020, net cash provided by financing activities was \$301.4 million, consisting of \$244.0 million in proceeds from our follow-on public offering of common stock, net of commissions, underwriting discounts and offering costs, \$20.0 million in proceeds from the concurrent placement, net of issuance costs, \$12.1 million from the issuance of common stock and exercise of stock options, \$24.8 million from the issuance of common stock under the 2019 and 2020 Sales Agreements, and \$0.5 million in connection with the issuance of common stock under our ESPP plan.

During the nine months ended September 30, 2019, net cash provided by financing activities was \$61.1 million, consisting of \$60.5 million in proceeds from our public offering of common stock, net of commissions, underwriting discounts and offering costs, \$0.3 million in connection with the issuance of common stock under our ESPP plan and \$0.2 million from the issuance of common stock and exercise of stock options.

## ***Funding Requirements***

Our expenses may increase substantially in connection with our ongoing clinical development activities and our 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 expenses will increase substantially if and as we:

- complete the clinical development and prepare for commercialization of SER-109 for the prevention of recurrent CDI;
- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC;
- continue the clinical development of SER-301 for the treatment of UC;
- continue the clinical development of SER-401 in our Phase 1b clinical trial for use with checkpoint inhibitors in patients with metastatic melanoma;
- conduct research and initiate clinical development of SER-155 for the prevention of mortality due to GvHD in immunocompromised patients, including in patients receiving allo-HSCT;
- make strategic investments in manufacturing capabilities;
- make strategic investments in our research discovery and development platforms and capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- potentially establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- perform our obligations under our agreements with our 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 impact of the COVID-19 pandemic;
- the progress and results of our clinical studies and pre-clinical development;
- the cost of manufacturing clinical supplies of our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates and research activities;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales 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 pre-clinical 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 and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products 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 the COVID-19 pandemic 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 shareholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our shareholders' rights as common stockholders. Our loan and security agreement with Hercules currently includes, and any additional 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 shareholders' 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 or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

As noted above, the magnitude and duration of the COVID-19 pandemic and its impact on our liquidity and future funding requirements is uncertain as of the filing date of this Quarterly Report on Form 10-Q as this continues to evolve globally. See "Impact of Novel Coronavirus" above and "Risk Factors—Risks Related to Our Operations—The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition" in Part II, Item 1A of this Quarterly Report on Form 10-Q for a further discussion of the possible impact of the COVID-19 pandemic on our business.

#### *Contractual Obligations and Commitments*

The disclosure of our contractual obligations and commitments was included in our Annual Report. There have been no material changes from the contractual commitments and obligations previously disclosed in our Annual Report.

#### *Off-Balance Sheet Arrangements*

As of September 30, 2020, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

#### *Interest Rate Fluctuation Risk*

We are exposed to market risk related to changes in interest rates.

As of September 30, 2020, our cash, cash equivalents and investments consisted of cash and money market accounts. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, an immediate 10% change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

As of September 30, 2020, we had outstanding borrowings under the Term Loan Facility. We accrue interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 4.40%, and (ii) 9.65%. An immediate 10% change in the Prime Rate would not have a material impact on our debt-related obligations, financial position or results of operations.

**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 Chief Executive Officer and Principal Financial and Accounting Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, 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, or the Exchange Act). Based on that evaluation, our Chief Executive Officer and Principal Financial and Accounting Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2020.

***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, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 1. Legal Proceedings.****Opposition Proceeding**

On October 19, 2016, the European Patent Office granted European Patent No. 2 575 835 B1 to The University of Tokyo. On April 25, 2017, we filed a notice of opposition to this patent in the European Patent Office, 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 has appealed certain aspects of the Opposition Division's decision, as have we and other opponents.

**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 on Form 10-Q. If any of the following risks occur, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Results of Operations and Financial Condition." 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 are a development-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. Our net loss was \$70.3 million for the year ended December 31, 2019, and \$70.9 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of \$530.5 million. 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 collaboration agreements, and our term loan facility. We have devoted substantially all of our financial resources and efforts to developing our microbiome therapeutics platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We have not completed development of any of our product candidates, which we call Ecobiotic microbiome therapeutic candidates, or other drugs or biologics. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses may increase substantially as we:

- complete the clinical development and prepare for commercialization of SER-109 for the prevention of recurrent CDI;
- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC;
- continue the clinical development of SER-301 for the treatment of UC;
- continue the clinical development of SER-401 in our Phase 1b clinical trial for use with checkpoint inhibitors in patients with metastatic melanoma;
- conduct research and initiate clinical development of SER-155 for the prevention of mortality due to GvHD in immunocompromised patients, including in patients receiving allo-HSCT;
- make strategic investments in manufacturing capabilities;
- make strategic investments in our research discovery and development platforms and capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- potentially establish a sales and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- perform our obligations under our agreements with our 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 eventually 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 may 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, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

***We will need additional funding in order to complete development of our product candidates and commercialize our products, if approved. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.***

Our expenses may increase in connection with our ongoing activities, particularly as we continue the clinical development of SER-109, continue the clinical development of SER-287, including conducting the Phase 2b clinical study, continue clinical studies of SER-301 and SER-401, and continue to research, develop and initiate clinical trials of SER-155 and our other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. 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 when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We expect that our cash, cash equivalents and investments as of September 30, 2020 will be sufficient to fund our operating expenses, debt service obligations and capital expenditure requirements for at least the next 12-months from the issuance of our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, subject to compliance with the conditions and covenants of our Loan and Security Agreement with Hercules Capital, Inc. This estimate excludes net cash flows from future business development activities. In addition, the specifics of existing and future clinical trial activities could impact capital requirements and cash projections. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the impact of the COVID-19 pandemic;
- the progress and results of our clinical studies;
- the cost of manufacturing clinical supplies for our product candidates;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other product candidates;
- the revenue, if any, received from commercial sales 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 the COVID-19 pandemic 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 the commercialization of any product candidates, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of 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. We have not yet demonstrated our ability to obtain regulatory approvals, 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.

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

***Other than SER-109 and SER-287, we are early in our development efforts and may not be successful in our efforts to use our microbiome therapeutics platform to build a pipeline of product candidates and develop marketable drugs.***

We are using our microbiome therapeutics platform to develop Ecobiotic® microbiome therapeutic candidates. We are at an early stage of development and our platform has not yet, and may never, lead to approvable or marketable drugs. We are developing additional product candidates that we intend to be used to prevent 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 preventing 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 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 products, 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 products, 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 products, 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 products following approval; and
- maintaining and growing an organization of scientists and business people who can develop and commercialize our products and technology.

If we do not successfully develop and commercialize product candidates we will not be able to obtain product revenue 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 microbiome therapeutics, which is an unproven approach to therapeutic intervention.***

All of our product candidates are based on microbiome therapeutics, a novel class of live biotherapeutic drug candidates, which are consortia of microbes designed to treat disease by modulating the microbiome to repair the function of a disease susceptible microbiome to a non-disease state. We have not, nor to our knowledge has any other company, received regulatory approval for, or manufactured on a commercial scale, a therapeutic based on this approach. We cannot be certain that our approach will lead to the development of approvable or marketable products or that we will be able to manufacture at commercial scale, if approved. In addition, our Ecobiotic microbiome therapeutic candidates may have different effectiveness rates in various indications and in different geographical areas. Finally, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of products based on microbiome therapeutics, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our product candidates.

Our microbiome therapeutics platform relies on third parties for biological materials, including human stool. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these biological materials could materially adversely affect our business. For example, if any supplied biological materials are contaminated with disease organisms, we would not be able to use such biological materials. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Improper storage of these materials, by us or any third-party suppliers, may require us to destroy some of our materials or products, which could delay the development or 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 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 failed clinical trial can occur at any stage of testing. 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 regulators, will require us to conduct before we may successfully gain approval to market any of our other product candidates. Prior to approving a new therapeutic product, the FDA generally requires that safety and efficacy 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:

- regulators or institutional review boards 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;
- regulators or institutional review boards 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;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- regarding trials managed by any 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.

For example, in March 2020, as a result of the COVID-19 pandemic, we halted further enrollment of the recently completed ECOSPOR III trial with 182 patients enrolled. Following receipt of the Phase 3 top-line data from ECOSPOR III, the FDA reaffirmed its prior guidance that at least 300 patients will be required for the safety database for SER-109, and we are now actively enrolling patients in our SER-109 open-label study to expand the safety database to meet the FDA guidance. We may also be required to treat additional patients with SER-109 in order to generate a sufficient safety database to allow us to seek approval of SER-109. Additional clinical trials or changes in our development plans could cause us to incur significant development costs, delay or prevent the commercialization of SER-109 or otherwise adversely affect our business. In addition, prolonged disruptions caused by the COVID-19 pandemic could severely impact our preclinical studies and clinical trials, including by causing further difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. See “—Risks Related to Our Operations—The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition.”

Our product development costs will increase if we continue to experience delays in clinical testing or marketing approvals. 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.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. There is a limited number of patients from which to draw for clinical studies.

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, including the use of unapproved fecal microbiota transplant, or FMT, for CDI;
- 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.

We are now actively enrolling patients in our SER-109 open-label study, which also admits patients with a single recurrence of CDI, to expand the safety database to meet the FDA guidance of at least 300 patients. Enrollment delays in our clinical trials result in increased development costs for our product candidates, which could cause the value of our company to decline and limit our ability to obtain additional financing. See “—Risks Related to Our Operations—The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition.”

***It may take longer than anticipated to generate sufficient safety data to allow us to gain approval of SER-109.***

Subsequent to the receipt of the Phase 3 top-line data, the FDA reaffirmed its prior guidance that at least 300 patients will be required for the safety database for SER-109. We may also be required to treat additional patients with SER-109 in order to generate a sufficient safety database to allow us to seek approval of SER-109. The need to conduct additional clinical trials of SER-109 and any delay in gaining regulatory approval of SER-109 would increase our development costs and could cause the value of our Company to decline and limit our ability to obtain additional financing.

***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.***

From time to time, we may publicly disclose interim, top-line or preliminary data from our 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.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become 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 agencies, 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 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 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 by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate in any jurisdiction will prevent us from commercializing the product candidate in that jurisdiction and may affect our plans for 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. 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 Ecobiotic microbiome therapeutic 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 agency'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. There may also be interruptions or delays in the operations of the FDA or other foreign regulatory authorities due to the COVID-19 pandemic, which may impact approval timelines. Regulatory authorities have substantial discretion in the approval process and may refuse to accept 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 is 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 agency 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 filing 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 agency 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 agency 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 agency, may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent 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 Ecobiotic microbiome therapeutic 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 may 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 FDA Fast Track designation. SER-287 received Fast Track designation from the FDA for the induction and maintenance of clinical remission in adults with mild-to-moderate UC. Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. 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 designation 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.***

We have received Breakthrough Therapy designation for SER-109, and we may seek a Breakthrough Therapy designation for our other 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 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 are also eligible for rolling review of the associated marketing application, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as priority review, where the agency aims to act on the application within eight months.

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 the Breakthrough Therapy designation for SER-109 or any future designation we receive is no longer supported by subsequent data, the FDA may rescind the designation.

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

We have obtained orphan drug designation from the FDA for SER-109 for recurrent CDI and SER-287 for pediatric ulcerative colitis and may seek orphan drug designation and exclusivity 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.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug or biologic for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines 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.

Orphan drug exclusivity for a product may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes 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.

***Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns 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 to review and or 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 ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency 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 agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global pandemic of COVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to 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.

### **Risks Related to our Dependence on Third Parties and Manufacturing**

***The Collaboration and License Agreement, or the License Agreement, with Nestec Ltd., or NHS, is important to our business. If we or NHS fail to adequately perform under the License Agreement, or if we or NHS terminate the License Agreement, the development and commercialization of our CDI and IBD product candidates, including SER-109, SER-287, and SER-301, would be delayed or terminated and our business would be adversely affected.***

The License Agreement may be terminated:

- by NHS in the event of serious safety issues related to SER-109, SER-287, SER-301 or other specific products added under the License Agreement, or, collectively, the NHS Collaboration Products;
- by us if NHS challenges the validity or enforceability of any of our licensed patents; and
- by either NHS or us in the event of the other party's uncured material breach or insolvency.

Upon termination of the License Agreement, all licenses granted to NHS by us will terminate, and all rights in and to the NHS Collaboration Products held by NHS will revert to us. If we commit a material breach of the License Agreement, NHS may elect not to terminate the License Agreement but instead apply specified adjustments to its payment obligations and other terms and conditions of the License Agreement. If NHS were to make such adjustments, the funding from and benefits of the License Agreement could be diminished, which could adversely affect our financial condition. Unless the License Agreement is terminated by us for NHS' uncured material breach, upon termination of the License Agreement, NHS will be eligible to receive post-termination royalties from us until NHS has recouped certain development costs related to the NHS Collaboration Products and specified percentages of any milestone payments paid to us under the License Agreement prior to termination, which could have a material adverse effect on our business.

Termination of the License Agreement could cause significant delays in our product development and commercialization efforts that could prevent us from commercializing our CDI and IBD product candidates, outside of the United States and Canada, without first expanding our internal capabilities or entering into another agreement with a third party. Any alternative collaboration or license could also be on less favorable terms to us. In addition, under the License Agreement, NHS agreed to provide funding for certain clinical development activities. If the License Agreement were terminated, we may need to refund those payments and seek additional financing to support the research and development of any terminated products or discontinue any terminated products, which could have a material adverse effect on our business.

Under the License Agreement, we are dependent upon NHS to successfully commercialize any NHS Collaboration Products outside of the United States and Canada. We cannot directly control NHS' commercialization activities or the resources it allocates to our product candidates. Our interests and NHS' interests may differ or conflict from time to time, or we may disagree with NHS' level of effort or resource allocation. NHS may internally prioritize our product candidates differently than we do or it may not allocate sufficient resources to effectively or optimally commercialize them. If these events were to occur, our business would be adversely affected.

***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 contract research organizations, or 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, 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. Other countries' regulatory agencies 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 commercialization of our products, 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 for preclinical and clinical testing and 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 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 commercialization efforts.

We may be unable to establish any agreements with third-party manufacturers on acceptable terms or at all. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- 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. The contract manufacturers we rely on to produce our product candidates have never produced an FDA-approved therapeutic. If our manufacturers are unable to comply with cGMP regulation or if the FDA or other regulators 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 that might be capable of manufacturing our products. 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 commercialization of our product candidates.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. Except for our clinical production facility in Massachusetts, we do not currently have arrangements in place for redundant supply of product. We do not currently have a second source for 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 commercialization efforts. Moreover, as a result of the COVID-19 pandemic, third-party manufacturers may be affected, which could disrupt their activities and as a result we could face difficulty sourcing key components necessary to produce supply of our product candidates, which may negatively affect our preclinical and clinical development activities.

***We have no experience manufacturing our product candidates at commercial scale, 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 and a portion of the manufacture of Ecobiotic microbiome therapeutics. The FDA and other comparable foreign regulatory agencies 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. We have not yet had any of our manufacturing facilities inspected.

We may establish a manufacturing facility for our product candidates for production at a commercial scale. We have no experience in commercial-scale manufacturing of our product candidates. We currently intend to develop our manufacturing capacity in part by expanding our current facility or building additional facilities. This activity will require substantial additional funds and we would need to hire and train significant numbers of qualified employees to staff these facilities. We may not be able to develop commercial-scale manufacturing facilities that are adequate to produce materials for additional later-stage clinical trials or commercial use.

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.

In addition, some of our product candidates require donor material, of which we may not be able to collect sufficient quantities for commercial-scale or other manufacturing.

## Risks Related to Commercialization of Our Product Candidates and Other Legal Matters

***Even if any of our product candidates receives marketing approval, it 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.***

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current CDI treatment involves the use of antibiotics that are well established in the medical community or the use of FMT, and physicians may continue to rely on these treatments and our competitors and physicians may continue to seek to standardize and implement this procedure. If our product candidates receive approval but do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our approved product candidates, if any, will depend on a number of factors, including:

- their efficacy, safety and other potential advantages compared to alternative treatments;
- the clinical indications for which our 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 together with other medications;
- interactions of our products with other medicines patients are taking; and
- the ability of patients to take our products.

***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 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 no experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements with third parties to perform sales and marketing functions and we may not be successful in doing so.

In the future, we expect to build a focused sales and marketing infrastructure to market or co-promote our product candidates in the United States and potentially elsewhere, if and when they are approved. 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 any product launch. 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 cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our 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 rely and may increasingly rely on third parties, including NHS, to sell, market and distribute our product candidates. 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 product revenue and 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 products 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 of products, including microbiome therapeutics, for reducing CDI and other 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. For example, FMT is a procedure that has resulted in reports of high cure rates for recurrent CDI and our competitors and physicians may continue to seek to standardize and implement this procedure. 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 may develop. Our competitors also may obtain FDA or other regulatory approval for their products 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 microbiome therapeutic 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 product candidates, 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 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 products may be difficult. We cannot be certain if and when we will obtain an adequate level of reimbursement for our products 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 the 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 will face an even greater risk if we commercially sell 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 any product candidates or products that we may develop;
- 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 any products that we may develop.

We currently hold \$5.0 million in product liability insurance coverage in the aggregate, with a per occurrence limit of \$5.0 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. 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.***

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, 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 12 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. 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 qualify for the 12-year period of 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. It is possible that Congress or the FDA may take these or other measures to reduce or eliminate periods of exclusivity. The BPCIA is complex and continues to be interpreted and implemented by the FDA. As a result, its ultimate impact is subject to uncertainty. The FDA has issued several guidance documents to date discussing the biosimilar pathway, and the FDA approved the first biosimilar under the BPCIA in March 2015. However, the FDA continues to implement the BPCIA, and such FDA implementation could have a material adverse effect on the future commercial prospects for our product candidates.

In Europe, 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 will 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 products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products 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 products in the European Union, or 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 or our collaborators 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 products in any market.

***Any product candidate for which we obtain marketing approval could be subject to post- marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.***

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 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. Accordingly, we 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 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 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. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products outside of their approved indications, we may be subject to enforcement action for off-label marketing or promotions. Violations of the FDA's restrictions relating to the promotion of prescription drugs 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 agency or we later discover previously unknown problems with our products, such as adverse events of unanticipated severity or frequency, problems with manufacturers or manufacturing processes, or failure to comply with regulatory requirements, the regulatory agency may impose restrictions on the products or us, including requiring withdrawal of the product from the market. Any failure to comply with applicable regulatory requirements may yield various results, including:

- litigation involving patients taking our products;
- 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;
- 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 regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. For example, in December 2016, the 21<sup>st</sup> Century Cures Act was signed into law, which is intended, among other things, to modernize the regulation of biologics and to spur innovation, though its ultimate implementation remains unclear. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues. If regulatory sanctions are applied or if regulatory approval is withheld or withdrawn, the value of our company and our operating results will be adversely affected.

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 adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. For example, certain policies of the current Presidential administration may impact our business and industry. Namely, the current Presidential administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval or marketing applications. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. 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 lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

***Our 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 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 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 products for which we 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. 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 (described below);
- the False Claims Act, imposes, among other things, impose 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- 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 other healthcare professionals beginning 2022 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;
- 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 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; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. By way of example, the California Consumer Privacy Act, or CCPA, effective January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. In Europe, the General Data Protection Regulation, or GDPR, which went into effect in May 2018, introduces strict requirements for processing the personal data of European Union data subjects. 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 or 4% of the annual global revenues of the noncompliant company, whichever is greater.

The risk of our 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 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.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and 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.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates 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;
- 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;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical 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 and Congressional challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act of 2017 was enacted, which, among other things, repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the ACA will impact the ACA and our business.

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, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2029 unless additional Congressional action is taken. On January 2, 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. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain.

We expect that the ACA, as well as 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 generate revenue, attain profitability, or commercialize our product candidates, if approved.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly active in 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm 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.

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 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 countries of the EU, the pricing of prescription 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. If coverage and reimbursement of our products are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, 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 products. 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 a very early stage. For some 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 and options to obtain 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 currently have, and may have in the future, certain funding arrangements, such as our grant from CARB-X to support certain work for SER-155. 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. In addition, under our CARB-X grant, we may be required in the future to grant a private sector charitable organization a license to certain of our intellectual property related to the subject matter of the CARB-X grant if, after a certain period of time, we are not developing and have not licensed a third party to develop the applicable technology for certain indications in a given country, and the organization wishes to do so. 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 option to license certain IP from MD Anderson and exclusive licenses to certain IP from Memorial Sloan Kettering Cancer Center). Of these, 15 applications have been nationalized and 1 is pending at the provisional stage. While we have obtained 13 issued U.S. patents to date, 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, such claims would not prevent a third party from commercializing alternative compositions that do not include both of the bacterial populations claimed in pending applications, potential applications or patents that have or may issue. There can be no assurance that any such alternative composition will not be equally effective. Further, given that our SER-109 product candidate is a complex composition with some variation from lot-to-lot and that, likewise, third-party compositions may have similar complexity and variability, it is possible that a patent claim may provide coverage for some but not all lots of a product candidate or third-party product. 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 products. In addition, given the early stage of prosecution of our portfolio, it may be some time before we understand 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 products, 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 has appealed certain aspects of the Opposition Division’s decision, as have we and other opponents. 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 products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products 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 our product candidates or any other products or product candidates;
- any of our pending patent applications will issue as patents at all;
- we will be able to successfully commercialize 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 products.***

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, only 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 issued 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 full impact of these decisions is not yet known. For example, in view of these and subsequent court decisions, the USPTO has issued various materials to patent examiners providing guidance for determining the patent eligibility of claims reciting laws of nature, natural phenomena or natural products. Our current product candidates include natural products, therefore, this decision and its interpretation by the courts and the USPTO may impact prosecution, defense and enforcement of our patent portfolio. On March 4, 2014, the USPTO issued a memorandum reflecting the USPTO's interpretation of the cases related to patent eligibility of natural products. The March 4, 2014 memorandum was superseded by interim guidance published on December 15, 2014. Additional guidance was published in July 2015 (July 2015 Update: Subject Matter Eligibility) and May 2016 (May 2016 Subject Matter Eligibility Update). 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 our collaborators, to develop, manufacture, market and sell our product candidates 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. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our technology, products or use of our products 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. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, 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, our products or the use of our products. 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 has appealed certain aspects of the Opposition Division's decision, as have we and other opponents.

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 products 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 products 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 products. 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.

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 products 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 products, 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.

***The COVID-19 pandemic caused by the novel strain of coronavirus has adversely impacted and could continue to adversely impact, our business, including our preclinical studies and clinical trials, results of operations and financial condition.***

In December 2019, a novel strain of coronavirus causing the COVID-19 disease was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices, restricted on-site staff to only those required on-site to execute their job responsibilities and limited the number of staff in any given research and development laboratory. On March 30, 2020, as a result of the COVID-19 pandemic, we halted further enrollment of the recently completed ECOSPOR III trial, and we are now actively enrolling patients in our SER-109 open-label study to expand the safety database to meet the FDA guidance of at least 300 patients. Additionally, SER-287 development activity was impacted by the COVID-19 pandemic and by multiple clinical sites halting non-essential procedures, including endoscopies. In recent months, the Company has observed an increase in ECO-RESET clinical site activity, the availability of endoscopies, and in the volume of clinical study subject screening, however the situation remains uncertain. We are continuing to monitor the impact of the COVID-19 pandemic on our operations and ongoing clinical development activity, including on the SER-401 Phase 1b study in metastatic melanoma. Mitigation activities to minimize COVID-19-related operation disruptions are ongoing, however, given the severity and evolving nature of the situation, the timing of the SER-401 Phase 1b clinical readout is uncertain. As a result of the COVID-19 outbreak, we may experience further disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA, which may impact approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns, global shipping delays or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.
- refusal of the FDA to accept data from clinical trials in affected geographies;
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans; and
- delays or difficulties with equity offerings due to disruptions and uncertainties in the securities market.

In addition, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak further impacts our business, including our preclinical studies and clinical trials, results of operations and financial condition will depend on future developments which are highly uncertain and cannot be predicted with confidence. Such factors include but are not limited to the duration of the outbreak, travel restrictions, quarantines, shelter-in-place orders and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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

We are highly dependent on Eric Shaff, our President and Chief Executive Officer, 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 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 the 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. 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. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***We may expand our operational capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of lead discovery and product development, regulatory affairs, clinical affairs and manufacturing and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage potential future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such potential growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***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, particularly after we are no longer an emerging growth company or a smaller reporting company. 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 may 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, 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.

***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 currently conduct clinical studies in Canada, Australia and New Zealand. We may conduct clinical studies in other countries as well. We currently plan to rely on collaborators, including NHS, to commercialize certain approved products outside of North America. 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, 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 products 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;
- 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 products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, 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.

***Our business and operations would suffer in the event of information technology and other system failures.***

Despite the implementation of a formal, comprehensive cyber-security program, our internal computer systems and data and those of our current and future contractors and consultants are vulnerable to damage or compromise from computer viruses, unauthorized access, ransomware, human error, loss of data privacy, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, there have been successful but immaterial cyber-attacks, and if such an event were to occur again in a more material manner and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our product candidates could be delayed.

***Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.***

We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. 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;
- additional exposure to cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration 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 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 may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

***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 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.

***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, including from the novel coronavirus SARS-CoV-2, which causes the COVID-19 disease, 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.

***Changes in U.S. tax law may materially adversely affect our financial condition, results of operations and cash flows.***

The Tax Cuts and Jobs Act of 2017, or TCJA, has significantly changed the U.S. federal income taxation of U.S. corporations. The TCJA remains unclear in many respects and has been, and may continue to be, the subject of amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, which have lessened or increased certain adverse impacts of the TCJA and may do so in the future. We continue to work with our tax advisors to determine the full impact that the TCJA will have on us. We urge our investors to consult with their legal and tax advisors with respect to the TCJA.

***Our ability to use our net operating loss carryforwards and research and development credits to offset future taxable income may be subject to certain limitations.***

As of December 31, 2019, we had net operating loss carryforwards, or NOLs, of \$266.5 million for federal income tax purposes and \$265.7 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our federal and state NOLs begin to expire in various amounts in 2035, provided that federal NOLs generated after December 31, 2017 will not be subject to expiration. As of December 31, 2019, we also had federal and state research and development and other tax credit carryforwards of approximately \$31.8 million and \$6 million, respectively, available to reduce future tax liabilities. Our 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 \$18.8 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. In addition, in general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, 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. 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 three year period. We believe we have experienced an ownership change in the past and 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 undergo an ownership change, 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. Under the TCJA, although the treatment of NOLs arising on or before December 31, 2017 has generally not changed, NOLs arising on or after January 1, 2018 will generally only be able to offset 80% of taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

***The terms of our credit facility place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.***

In October 2019, we entered into a loan and security agreement with Hercules pursuant to which a term loan facility in aggregate principal amount up to \$50.0 million, or the Term Loan Facility, is available to us in three tranches, subject to certain terms and conditions. We received the first tranche of \$25.0 million upon signing the agreement on October 29, 2019. We did not meet the milestone requirements for the second tranche under the Term Loan Facility, and as such, the additional second tranche amount of up to \$12.5 million is not available for us to borrow. The third tranche, which allows us to borrow an additional \$12.5 million, will be available upon Hercules' approval on or prior to June 30, 2021. The Term Loan Facility is secured by a lien on substantially all of our assets, other than intellectual property. We also agreed not to pledge or secure our intellectual property to others.

The Term Loan Facility includes affirmative and negative covenants and events of default applicable to us. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on our transferring collateral, making changes to the nature of our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, engaging in transactions with affiliates. The Term Loan Facility also includes a liquidity covenant that commences either October 31, 2020, or December 31, 2020 based upon our satisfaction of certain performance milestones. Events of default include, among other things and subject to customary exceptions: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the loan and security agreement with Hercules or other loan documents on a timely basis; (iii) failure to observe certain covenants under the loan and security agreement with Hercules; (v) occurrence of a material adverse effect; (vi) material misrepresentation by us; (vii) occurrence of any default under any other agreement involving material indebtedness; and (viii) certain material money judgments. If we default under the loan and security agreement, Hercules may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Any declaration by Hercules of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

### **Risks Related to Our Common Stock**

***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:

- 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;
- 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.

***Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or 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 66% of our outstanding voting stock. As a result, if these stockholders were to choose to act together, they would be able to control or 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 control or significantly influence the election of directors and 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 an “emerging growth company” and a “smaller reporting company,” and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.***

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until December 31, 2020. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to include audited financial statements in our selected financial data and in any future registration statements under the Securities Act for any period prior to the earliest audited financial statements presented in our registration statement on Form S-1 for the initial public offering of our common stock;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved and from having to disclose the ratio of compensation of our chief executive officer to the median compensation of our employees.



In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also 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 million measured on the last business day of our second fiscal quarter and (ii) our annual revenues are more than \$100 million during the most recently completed fiscal year and the value of our voting and non-voting common shares held by non-affiliates is more than \$700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, 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 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.

***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.

***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 our board of directors 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 of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- 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 of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors 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 of directors 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 of directors, the chief executive officer, the president or the board of directors, 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 of directors 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. Furthermore, 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. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision 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 to be inapplicable or unenforceable in such action.

***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, our loan and security agreement with Hercules Capital currently prohibits us from paying dividends on our equity securities, and any future debt agreements may likewise 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.

**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.**

None.

**Item 6. Exhibits.**

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		Filing Date	Filed/ Furnished Herewith
			File No.	Exhibit		
3.1	<a href="#">Restated Certificate of Incorporation, filed on July 1, 2015</a>	8-K	001-37465	3.1	7/1/15	
3.2	<a href="#">Amended and Restated Bylaws</a>	8-K	001-37465	3.2	7/1/15	
10.1#	<a href="#">Employment Agreement, dated October 13, 2020, by and between the Registrant and David S Ege</a>					*
10.2	<a href="#">Securities Purchase Agreement, dated August 12, 2020 by and between the Company and Société des Produits Nestlé S.A.</a>	8-K	001-37465	10.1	8/14/20	
31.1	<a href="#">Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer</a>					*
31.2	<a href="#">Rule 13a-14(a)/15d-14(a) Certification of Principal Financial and Accounting Officer</a>					*
32.1	<a href="#">Section 1350 Certification of Chief Executive Officer</a>					**
32.2	<a href="#">Section 1350 Certification of Principal Financial and Accounting Officer</a>					**
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					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

\* Filed herewith.

\*\* Furnished herewith.

# Indicates management contract or compensatory plan.

**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 9, 2020

By: /s/ Marcus Chapman  
Marcus Chapman  
Senior Vice President, Finance  
*(Principal Financial and Accounting Officer)*

## EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement"), dated as of October 13, 2020, is made by and between Seres Therapeutics, Inc., a Delaware corporation (together with any successor thereto, the "Company"), and David S. Ege, Ph.D. ("Executive") (collectively referred to as the "Parties" or individually referred to as a "Party").

## RECITALS

- A. It is the desire of the Company to assure itself of the services of Executive by entering into this Agreement.
- B. Executive and the Company mutually desire that Executive be employed by the Company on the terms herein provided, commencing on October 19, 2020 or another date mutually agreed by the Parties (the date Executive actually commences such employment, the "Effective Date").
- C. This Agreement will become effective upon the Effective Date.

## AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

**1. Employment.**

(a) General. Effective on the Effective Date, the Company shall employ Executive and Executive shall remain in the employ of the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided.

(b) At-Will Employment. The Company and Executive acknowledge that Executive's employment is and shall continue to be at-will, as defined under applicable law, and that Executive's employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This "at-will" nature of Executive's employment shall remain unchanged during Executive's tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive's employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the "Term") shall commence on the Effective Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. Executive shall serve as Executive Vice President and Chief Technology Officer of the Company, reporting directly to the Chief Executive Officer ("CEO") of the Company, with such responsibilities, duties and authority normally associated with such positions and as may from time to time be assigned to Executive by the CEO of the Company. Executive shall devote substantially all of Executive's working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the Board (as defined below), provided that Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, (ii) participate in trade associations, and (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case as amended from time to time, as set forth in writing, and as delivered or made available to Executive (each, a "Policy").

**2. Compensation and Related Matters.**

(a) Annual Base Salary. During the Term, Executive shall receive a base salary at a rate of \$375,000 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-

rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board of Directors of the Company or an authorized committee of the Board (in either case, the "Board") (such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

(b) Bonus. During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 40% of Executive's Annual Base Salary. The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board and may be pro-rated for any partial year of employment. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) Benefits. During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company (including medical, dental and 401(k) plans), consistent with the terms thereof and as such plans, programs and arrangements may be amended from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(d) Vacation. During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) Business Expenses. During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) Key Person Insurance. At any time during the Term, the Company shall have the right to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably cooperate with the Company in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document, and shall have no interest in any such policy.

(g) Equity. Subject to approval by the Board, the Company will grant Executive an option (the "Option") under the Company's 2015 Incentive Award Plan (the "Plan") to purchase 200,000 shares of the Company's common stock (subject to adjustment for corporate events as set forth in the Plan) at an exercise price per share equal to the per share fair market value of the Company's common stock on the date of grant, as determined in accordance with the Plan. The Option will vest as to 25% of the shares subject to the Option on the first anniversary of the Effective Date and as to an additional 6.25% of such shares upon Executive's completing each three months of continuous service to the Company thereafter. In all respects, the Option will be governed by and subject to the terms of the Plan and a separate stock option agreement to be entered into between Executive and the Company.

(h) Relocation Assistance. The Company will reimburse Executive for, or directly pay on Executive's behalf, (i) up to \$62,500 of reasonable moving and commuting expenses Executive incurs between the Effective Date and December 31, 2021 (the "2021 Relocation Assistance") and (ii) up to \$62,500 of reasonable moving and commuting expenses Executive incurs between January 1, 2022 and December 31, 2022 (the "2022 Relocation Assistance," and, together with the 2021 Relocation Assistance, collectively, the "Relocation Assistance"). If less than the maximum 2021 Relocation Assistance amount is paid to Executive, the Company will consider in 2022 or thereafter whether to provide additional relocation assistance to Executive. The Company will also provide Executive with an additional payment (a "Gross-Up Payment") in an amount such that, after payment by Executive of all income and employment taxes imposed on the Gross-Up Payment, Executive retains from the Gross-Up Payment an amount equal to all of the income and employment taxes imposed on the Relocation Assistance Executive receives. All payments to Executive or for Executive's benefit under this Section shall be subject to Section 9(l), except that

notwithstanding anything in such Section to the contrary, (1) Executive will promptly, and in no event later than December 15, 2021, submit all requests for 2021 Relocation Assistance payments, together with any supporting documentation that the Company reasonably requests, and the Company will make all 2021 Relocation Assistance payments during calendar year 2021, regardless of when the corresponding expenses were incurred, (2) Executive will promptly, and in no event later than December 15, 2022, submit all requests for 2022 Relocation Assistance payments, together with any supporting documentation that the Company reasonably requests, and the Company will make all 2022 Relocation Assistance payments during calendar year 2022, and (3) the Gross-Up Payment shall be paid no later than April 1 of the calendar year following the calendar year in which Executive submits the applicable income and employment taxes giving rise to such Gross-Up Payment and in accordance with Treas. Reg. § 1.409A-3(i)(1)(v). If Executive's employment with the Company ends due to Executive's resignation from the Company without Good Reason or the Company's termination of Executive for Cause, which, in either case, occurs within one (1) year after the Effective Date, then, (x) unless such a termination of employment occurs following a Change in Control (as defined herein), Executive shall be required to repay any Relocation Assistance or Gross-Up Payment, less any commuting-specific expenses, to the Company within 90 days following such termination of employment, in an amount to be prorated for that portion of such one year period that Executive did not complete and (y) the Company may, but shall not be required to, offset any amounts required to be repaid under the foregoing clause (x) against any amounts otherwise owed to Executive by the Company to the extent that such offset will not cause a violation of, or result in any additional tax or penalty under, Section 409A (as defined below).

(i) Sign-On Bonus. Executive will be paid a total sign-on bonus of \$65,000 (the "Sign-On Bonus"), which shall be paid in a single lump sum on the first payroll date after commencement of employment with the Company.

### 3. Termination.

Executive's employment hereunder may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances:

(a) Circumstances.

(i) *Death*. Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability*. If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause*. The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause*. The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company for Good Reason*. Executive may resign Executive's employment with the Company for Good Reason, as defined below.

(vi) *Resignation from the Company Without Good Reason*. Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to paragraph (a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least forty-five (45) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of

Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company in its sole discretion. The failure by the Company to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause shall not waive any right of the Company hereunder or preclude the Company from asserting such fact or circumstance in enforcing the Company's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expenses owed to Executive pursuant to Section 2(e) and Section 2(h); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the "Company Arrangements"). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive's rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive's employment hereunder. In the event that Executive's employment is terminated by the Company for any reason, Executive's sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive's employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

#### **4. Severance Payments.**

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive's employment shall terminate as a result of Executive's death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(vi) for Executive's resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company for Good Reason. If Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, then, subject to Executive signing on or before the 21<sup>st</sup> day following Executive's Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the "Release"), and Executive's continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to the Annual Base Salary, payable in the form of salary continuation in regular installments over the 12-month period following the date of Executive's Separation from Service (the "Severance Period") in accordance with the Company's normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company's fiscal year prior to the fiscal year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company; and

(iii) if Executive elects to receive continued medical, dental or vision coverage under one or more of the Company's group healthcare plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive's covered dependents under such plans during the period commencing on Executive's Separation from Service and ending upon the earliest of (X) the last day of the



Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility). Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's and Executive's covered dependents' group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), less the amount Executive would have had to pay to receive group health coverage for Executive and his or her covered dependents based on the cost sharing levels in effect on the Date of Termination, which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which the Date of Termination occurs and shall end on the earlier of (X) the last day of the Severance Period, (Y) the date that Executive and/or Executive's covered dependents become no longer eligible for COBRA or (Z) the date Executive becomes eligible to receive healthcare coverage from a subsequent employer (and Executive agrees to promptly notify the Company of such eligibility).

(c) **Change in Control.** Notwithstanding anything to the contrary in Section 4(b), in the event Executive's employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive's resignation for Good Reason, in either case, within 60 days prior to or 12 months following the date of a Change in Control, subject to Executive signing on or before the 21<sup>st</sup> day following Executive's Separation from Service, and not revoking, the Release, and Executive's continued compliance with Section 5, Executive shall be entitled to receive, (i) without duplication, the payments and benefits described in Section 4(b); and (ii) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on the passage of time shall immediately become 100% vested (for the avoidance of doubt, with any such awards that vest in whole or in part based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement).

(d) **Survival.** Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive's employment and the termination of the Term.

5. **Restrictive Covenants.** As a condition to the effectiveness of this Agreement, Executive will execute and deliver to the Company prior to the Effective Date the Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement attached as Exhibit B (the "Proprietary Information Agreement"). Executive agrees to abide by the terms of the Proprietary Information Agreement, which are hereby incorporated by reference into this Agreement. Executive acknowledges that the provisions of the Proprietary Information Agreement will survive the termination of Executive's employment and the termination of the Term for the periods set forth in the Proprietary Information Agreement.

6. **Assignment and Successors.**

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise), and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personnel and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive's death by giving written notice thereof to the Company.

7. **Certain Definitions.**

(a) **Cause.** The Company shall have “Cause” to terminate Executive’s employment hereunder upon:

(i) Executive’s failure to (A) substantially perform Executive’s duties with the Company (other than any such failure resulting from Executive’s Disability) or (B) comply with, in any material respect, any of the Company’s Policies;

(ii) the Board’s determination that Executive failed in any material respect to carry out or comply with any lawful and reasonable directive of the Board;

(iii) Executive’s breach of a material provision of this Agreement;

(iv) Executive’s conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;

(v) Executive’s unlawful use (including being under the influence) or possession of illegal drugs on the Company’s (or any of its affiliate’s) premises or while performing Executive’s duties and responsibilities under this Agreement; or

(vi) Executive’s commission of an act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates.

(b) **Change in Control.** “Change in Control” shall have the meaning set forth in the version of the Seres Therapeutics, Inc. 2015 Incentive Award Plan in effect on the Effective Date.

(c) **Code.** “Code” shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) **Date of Termination.** “Date of Termination” shall mean (i) if Executive’s employment is terminated by Executive’s death, the date of Executive’s death; or (ii) if Executive’s employment is terminated pursuant to Section 3(a)(ii)–(vi), either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) **Disability.** “Disability” shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company’s employees, “disability” as defined in such long-term disability plan for the purpose of determining a participant’s eligibility for benefits, *provided, however*, if the long-term disability plan contains multiple definitions of disability, “Disability” shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, “Disability” shall mean Executive’s inability to perform, with or without reasonable accommodation, the essential functions of Executive’s positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive’s legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive’s Disability.

(f) **Good Reason.** For the sole purpose of determining Executive’s right to severance payments and benefits as described above, Executive’s resignation will be for “Good Reason” if Executive resigns within ninety days after any of the following events, unless Executive consents to the applicable event: (i) a decrease in Executive’s Annual Base Salary, other than a reduction in Annual Base Salary of less than 10% that is implemented in connection with a contemporaneous reduction in annual base salaries affecting other senior executives of the Company, (ii) a material decrease in Executive’s authority or areas of responsibility as are commensurate with Executive’s title or positions, or (iii) the relocation of Executive’s primary office to a location more than 50 miles from the Boston

metropolitan area. Notwithstanding the foregoing, no Good Reason will have occurred unless and until Executive has: (a) provided the Company, within 60 days of Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written-notice stating with specificity the applicable facts and circumstances underlying such finding of Good Reason; and (b) provided the Company with an opportunity to cure the same within 30 days after the receipt of such notice.

## **8. Parachute Payments.**

(a) Notwithstanding any other provisions of this Agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4(b) and Section 4(c) hereof, being hereinafter referred to as the "Total Payments"), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro-rata basis of any cash severance payments that are exempt from Section 409A of the Code ("Section 409A"), (ii) reduction on a pro-rata basis any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro-rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro-rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the "Independent Advisors"). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the "base amount" (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned immediately by Executive to the Company.

## **9. Miscellaneous Provisions.**

(a) Governing Law. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction, and where applicable, the laws of the United States.

(b) Validity. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) Notices. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

- (i) If to the Company, the Chief Financial Officer at its headquarters,
- (ii) If to Executive, at the last address that the Company has in its personnel records for Executive, or
- (iii) at any other address as any Party shall have specified by notice in writing to the other Party.

(d) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile shall be deemed effective for all purposes.

(e) Entire Agreement. The terms of this Agreement, and the Proprietary Information Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) Amendments; Waivers. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided, however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) No Inconsistent Actions. The Parties hereto shall not voluntarily undertake or fail to undertake any action or course of action inconsistent with the provisions or essential intent of this Agreement. Furthermore, it is the intent of the Parties hereto to act in a fair and reasonable manner with respect to the interpretation and application of the provisions of this Agreement.

(h) Construction. This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) “and” and “or” are each used both conjunctively and disjunctively; (iii) “any,” “all,” “each,” or “every” means “any and all,” and “each and every”; (iv) “includes” and “including” are each “without limitation”; (v) “herein,” “hereof,” “hereunder” and other similar compounds of the word “here” refer to the entire Agreement and not to any particular paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(i) Arbitration. Any controversy, claim or dispute arising out of or relating to this Agreement, shall be settled solely and exclusively by a binding arbitration process administered by JAMS/Endispute in Boston, Massachusetts. Such arbitration shall be conducted in accordance with the then-existing JAMS/Endispute Rules of Practice and Procedure, with the following exceptions if in conflict: (i) one arbitrator who is a retired judge shall be chosen by JAMS/Endispute; (ii) each Party to the arbitration will pay one-half of the expenses and fees of the arbitrator, together with other expenses of the arbitration incurred or approved by the arbitrator; and (iii) arbitration may proceed in the absence of any Party if written notice (pursuant to the JAMS/Endispute rules and regulations) of the proceedings has been given to such Party. Each Party shall bear its own attorney’s fees and expenses; provided

that the arbitrator may assess the prevailing Party's fees and costs against the non-prevailing Party as part of the arbitrator's award. The Parties agree to abide by all decisions and awards rendered in such proceedings. Such decisions and awards rendered by the arbitrator shall be final and conclusive. All such controversies, claims or disputes shall be settled in this manner in lieu of any action at law or equity; *provided, however*, that nothing in this subsection shall be construed as precluding the bringing of an action for injunctive relief or specific performance as provided in this Agreement. This dispute resolution process and any arbitration hereunder shall be confidential and neither any Party nor the neutral arbitrator shall disclose the existence, contents or results of such process without the prior written consent of all Parties, except where necessary or compelled in a Court to enforce this arbitration provision or an Award from such arbitration or otherwise in a legal proceeding. If JAMS/Endispute no longer exists or is otherwise unavailable, the Parties agree that the American Arbitration Association ("AAA") shall administer the arbitration in accordance with its then-existing rules as modified by this subsection. In such event, all references herein to JAMS/Endispute shall mean AAA. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by Court action instead of arbitration.

(j) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(k) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on an opinion of counsel if any questions as to the amount or requirement of withholding shall arise.

(l) Section 409A.

(i) *General*. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service*. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is considered nonqualified deferred compensation under Section 409A and is designated under this Agreement as payable upon Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4 shall not be paid, or, in the case of installments, shall not commence payment, until the thirtieth (30th) day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee*. Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence

shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements.* To the extent that any reimbursements under this Agreement are subject to Section 409A, (i) any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred; (ii) Executive shall submit Executive's reimbursement request promptly following the date the expense is incurred, (iii) the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and (iv) Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments.* Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

**10. Executive Acknowledgement.**

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

**SERES THERAPEUTICS, INC.**

By: /s/ Eric Shaff\_  
Name: Eric Shaff  
Title: President and Chief Executive Officer

/s/ David Ege  
David S. Ege, Ph.D.

*[Signature Page to Employment Agreement]*

## EXHIBIT A

### Separation Agreement and Release

This Separation Agreement and Release (“Agreement”) is made by and between David S. Ege, Ph.D. (“Executive”) and Seres Therapeutics, Inc. (the “Company”) (collectively referred to as the “Parties” or individually referred to as a “Party”). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Employment Agreement, dated as of [\_\_\_\_\_, 2020] (the “Employment Agreement”); and

WHEREAS, in connection with Executive’s termination of employment with the Company or a subsidiary or affiliate of the Company effective \_\_\_\_\_, 20\_\_, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive’s employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive’s ownership of vested equity securities of the Company or Executive’s right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the “Retained Claims”).

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive’s execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section 4(b) and/or Section 4(c) of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their respective current and former officers, directors, equity holders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the “Releasees”). Executive, on Executive’s own behalf and on behalf of any of Executive’s affiliated companies or entities and any of Executive’s or their respective heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive’s employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive’s right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state corporate law, and securities fraud under any state or federal law;



(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including, without limitation, the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation (including Executive's right to receive an award for information provided to any such government agencies), Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering monetary or other individual relief from the Company or any Releasee) in connection with any charge, investigation or proceeding, or any related complaint or lawsuit, filed by Executive or by anyone else on Executive's behalf before the federal Equal Employment Opportunity Commission or a comparable state or local agency), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law, and any Retained Claims. This release further does not release claims for breach of Section 3(c), Section 4(b) or Section 4(c) of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney

prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties expressly agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has 7 business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Post-Termination Obligations. Executive reaffirms Executive's continuing obligations under the Proprietary Information Agreement between Executive and the Company dated as of [\_\_\_\_], 2020, and, without limiting the foregoing, Executive remakes the non-competition covenants set forth in the Proprietary Information Agreement as if set forth herein. 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.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c) and 9(i) of the Employment Agreement.

8. Effective Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective upon the expiration of such seven business day period, so long as it has been signed by the Parties and has not been revoked by Executive before that date.

9. Trade Secrets; Whistleblower Protections. In accordance with 18 U.S.C. §1833, notwithstanding anything to the contrary in this Agreement, the Employment Agreement, the Proprietary Information Agreement or any other agreement between Executive and the Company or any of its subsidiaries in effect as of the date Executive receives this Agreement (together, the "Subject Documents"): (a) Executive will not be in breach of the Subject Document, and shall not be held criminally or civilly liable under any federal or state trade secret law (i) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (b) if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney, and may use the trade secret information in the court proceeding, if Executive files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order. Furthermore, the Parties agree that nothing in the Subject Documents prohibits Executive from reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation or releases or restrains Executive's right to receive an award for information provided to any such government agencies.

10. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

Dated: \_\_\_\_\_

\_\_\_\_\_  
David S. Ege, Ph.D.

**SERES THERAPEUTICS, INC.**

Dated: \_\_\_\_\_

By: \_\_\_\_\_  
Name:  
Title:

## EXHIBIT B

### **Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement**

In consideration and as a condition of my employment or continued employment (including my salary or wage, any bonus I may receive, and any equity granted to me) by Seres Therapeutics, Inc. (the "Company"), I hereby agree as follows:

- 1. Proprietary Information.** I agree that all information, whether or not in writing, whether or not disclosed before or after I was first employed by the Company, concerning the Company's business, technology, business relationships or financial affairs that the Company has not released to the general public (collectively, "Proprietary Information"), and all tangible embodiments thereof, are and will be the exclusive property of the Company. By way of illustration, Proprietary Information may include information or material that has not been made generally available to the public, such as: (a) *corporate information*, including plans, strategies, methods, policies, resolutions, notes, email correspondence, negotiations or litigation; (b) *marketing information*, including strategies, methods, customer identities or other information about customers, prospect identities or other information about prospects, or market analyses or projections; (c) *financial information*, including cost and performance data, debt arrangements, equity structure, investors and holdings, purchasing and sales data and price lists; and (d) *operational and technological information*, including plans, specifications, manuals, forms, templates, software, designs, methods, procedures, formulas, discoveries, inventions, improvements, biological or chemical materials, concepts and ideas; and (e) *personnel information*, including personnel lists, reporting or organizational structure, resumes, personnel data, compensation structure, performance evaluations and termination arrangements or documents. Proprietary Information includes, without limitation, (1) information received in confidence by the Company from its customers or suppliers or other third parties, and (2) all biological or chemical materials and other tangible embodiments of the Proprietary Information. Nothing in this Agreement shall prohibit me from reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 805 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation.
- 2. Recognition of Company's Rights.** I will not, at any time, without the Company's prior written permission, either during or after my employment, disclose or transfer any Proprietary Information to anyone outside of the Company, or use or permit to be used any Proprietary Information for any purpose other than the performance of my duties as an employee of the Company. I will cooperate with the Company and use my best efforts to prevent the unauthorized disclosure of all Proprietary Information. I will deliver to the Company all copies and other tangible embodiments of Proprietary Information in my possession or control upon the earlier of a request by the Company or termination of my employment.
- 3. Rights of Others.** I understand that the Company is now and may hereafter be subject to non-disclosure or confidentiality agreements with third persons which require the Company to protect or refrain from use of proprietary information. I agree to be bound by the terms of such agreements in the event I have access to such proprietary information.
- 4. Commitment to Company; Avoidance of Conflict of Interest.** While an employee of the Company, I will devote my full-time efforts to the Company's business and I will not engage in any other business activity that conflicts with my duties to the Company. I will advise the president of the Company or his or her nominee at such time as any activity of either the Company or another business presents me with a conflict of interest or the appearance of a conflict of interest as an employee of the Company. I will take whatever action is requested of me by the Company to resolve any conflict or appearance of conflict which it finds to exist.

5. **Developments.** I hereby assign and transfer and, to the extent any such assignment cannot be made at present, will assign and transfer, to the Company and its successors and assigns, all my right, title and interest in and to all Developments (as defined below) that: (a) are created, developed, made, conceived or reduced to practice by me (alone or jointly with others) or under my direction (collectively, "conceived") during the period of my employment and six (6) months thereafter and that relate to the business of the Company or to products, methods or services being researched, developed, manufactured or sold by the Company; or (b) result from tasks assigned to me by the Company; or (c) result from the use of premises, Proprietary Information or personal property (whether tangible or intangible) owned, licensed or leased by the Company (collectively, "Company-Related Developments"), and all patent rights, trademarks, copyrights and other intellectual property rights in all countries and territories worldwide claiming, covering or otherwise arising from or pertaining to Company-Related Developments (collectively, "Intellectual Property Rights"). I further agree that "Company-Related Developments" include, without limitation, all Developments that (i) were conceived by me before my employment, (ii) relate to the business of the Company or to products, methods or services being researched, developed, manufactured or sold by the Company, and (iii) were not subject to an obligation to assign to another entity when conceived. I will make full and prompt disclosure to the Company of all Company-Related Developments, as well as all other Developments conceived by me during the period of my employment and six (6) months thereafter. I acknowledge that all work performed by me as an employee of the Company is on a "work for hire" basis. I hereby waive all claims to any moral rights or other special rights which I may have or accrue in any Company-Related Developments. "Developments" mean inventions, discoveries, designs, developments, methods, modifications, improvements, processes, biological or chemical materials, algorithms, databases, computer programs, formulae, techniques, trade secrets, graphics or images, audio or visual works, and other works of authorship.

To preclude any possible uncertainty, I have set forth on Exhibit A attached hereto a complete list of Developments conceived by me before my employment that are not Company-Related Developments ("Prior Inventions"). I have also listed on Exhibit A all patent rights of which I am an inventor, other than those contained within Intellectual Property Rights ("Other Patent Rights"). If no such disclosure is attached, I represent that there are no Prior Inventions or Other Patent Rights. If, in the

course of my employment with the Company, I incorporate a Prior Invention into a Company product, process or research or development program or other work done for the Company, I hereby grant to the Company a nonexclusive, royalty-free, fully paid-up, irrevocable, perpetual, worldwide license (with the full right to sublicense through multiple tiers) to make, have made, modify, use, offer for sale, import and sell such Prior Invention. Notwithstanding the foregoing, I will not incorporate, or permit to be incorporated, Prior Inventions in any Company-Related Development without the Company's prior written consent.

I understand that to the extent this Agreement is required to be construed in accordance with the laws of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this Section will be interpreted not to apply to any invention which a court rules and/or the Company agrees falls within such classes.

6. **Documents and Other Materials.** I will keep and maintain adequate and current records of all Proprietary Information and Company-Related Developments conceived by me, which records will be available to and remain the sole property of the Company at all times. All files, letters, notes, memoranda, reports, records, data, sketches, drawings, notebooks, layouts, charts, quotations and proposals, specification sheets, program listings, blueprints, models, prototypes, materials or other written, photographic or other tangible material containing or embodying Proprietary Information, whether created by me or others, which come into my custody or possession, are the exclusive property of the Company to be used by me only in the performance of my duties for the Company. In the event of the termination of my employment for any reason, I will deliver to the Company all of the foregoing, and all other materials of any nature pertaining to the Proprietary Information of the Company and to my work, and will not take or keep in my possession any of the foregoing or any copies. Any property situated on the Company's premises and owned by the Company, including laboratory space, computers, disks and other storage media, filing cabinets or other work areas, is subject to inspection by the Company at any time with or without notice.

7. **Enforcement of Intellectual Property Rights.** I will cooperate fully with the Company, both during and after my employment with the Company, with respect to the procurement, maintenance and enforcement of Intellectual Property Rights, as well as all other patent rights, trademarks, copyrights and other intellectual property rights in all countries and territories worldwide owned by or licensed to the Company. I will sign, both during and after the term of this Agreement, all papers, including copyright applications, patent applications, declarations, oaths, assignments of priority rights, and powers of attorney, which the Company may deem necessary or desirable in order to protect its rights and interests in any Company-Related Development or Intellectual Property Rights. If the Company is unable, after reasonable effort, to secure my signature on any such papers, I hereby irrevocably designate and appoint each officer of the Company as my agent and attorney-in-fact to execute any such papers on my behalf, and to take any and all actions as the Company may deem necessary or desirable in order to protect its rights and interests in the same.

8. **Non-Competition and Non-Solicitation.** In order to protect the Company's Proprietary Information and good will, during my employment and for a period of twelve (12) months following the termination of my employment for any reason (the "Restricted Period"):

(a) in consideration of the offer of employment, my salary or wage, any bonus I may receive, and the equity granted to me in connection with commencement of employment with the Company, all of which I deem as fair and reasonable consideration for entering into this Agreement, I will not directly or indirectly, whether as owner, partner, shareholder, director, consultant, agent, employee, co-venturer or otherwise, engage, participate or invest in any business that develops, manufactures or markets microbiome therapeutics that are competitive with products or services of the Company, or that the Company has under development, or that are the subject of active planning at any time during my employment (collectively, the "Competitive Products"); provided that this will not prohibit any possible investment in publicly traded stock of a company representing less than one percent of the stock of such company and provided further that this provision shall apply only if I am an exempt employee (as that term is defined by the Fair Labor Standards Act) or if and when I subsequently become an exempt employee; and

(b) I will not directly or indirectly, in any manner, other than for the benefit of the Company, (i) call upon, solicit, divert or take away any of the customers, business or prospective customers of the Company or any of its suppliers, and/or (ii) solicit, entice or attempt to persuade any other employee or consultant of the Company to leave the services of the Company for any reason.

I acknowledge and agree that if I violate any of the provisions of this Section, in addition to any other remedies to which the Company may be entitled in law or equity, the running of the Restricted Period will be extended by the time during which I engage in such violation(s) or up to twenty four (24) months, whichever is longer.

I acknowledge and agree that the provisions of this agreement shall apply during and following my employment by the Company and shall not be affected by any change in my job duties, whether material or immaterial.

I further acknowledge and agree that I have the right and have had the opportunity to consult with an attorney prior to signing this Agreement.

9. **Government Contracts.** I acknowledge that the Company may have from time to time agreements with other persons or with the United States Government or its agencies which impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. I agree to comply with any such obligations or restrictions upon the direction of the Company. In addition to the rights assigned under Section 5, I also assign to the Company (or any of its nominees) all rights which I have or acquired in any Developments, full title to which is required to be in the United States under any contract between the Company and the United States or any of its agencies.

10. **Prior Agreements.** I hereby represent that, except as I have fully disclosed previously in writing to the Company, I am not bound by the terms of any agreement with any previous employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of my employment with the Company or to refrain from competing, directly or indirectly, with the business of such previous employer or any other party. I further represent that my performance of all the terms of this Agreement as an employee of the Company does not and will not breach any agreement to keep in confidence proprietary information, knowledge or data acquired by me in confidence or in trust prior to my employment with the Company. I will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employer or others.

11. **Remedies Upon Breach.** I understand that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and I consider them to be reasonable for such purpose. Any breach of this Agreement is likely to cause the Company substantial and irrevocable damage and therefore, in the event of such breach, the Company, in addition to such other remedies which may be available, will be entitled to specific performance and other injunctive relief.

12. **Use of Voice, Image and Likeness.** I give the Company permission to use my voice, image or likeness, with or without using my name, for the purposes of advertising and promoting the Company, or for other purposes deemed appropriate by the Company in its reasonable discretion, except to the extent expressly prohibited by law.

13. **Publications and Public Statements.** I will obtain the Company's written approval before publishing or submitting for publication any material that relates to my work at the Company and/or incorporates any Proprietary Information. To ensure that the Company delivers a consistent message about its products, services and operations to the public, and further in recognition that even positive statements may have a detrimental effect on the Company in certain securities transactions and other contexts, any statement about the Company which I create, publish or post during my period of employment and for six (6) months thereafter, on any media accessible by the public, including but not limited to electronic bulletin boards and Internet-based chat rooms, must first be reviewed and approved by an officer of the Company before it is released in the public domain.

14. **No Employment Obligation.** I understand that this Agreement does not create an obligation on the Company or any other person to continue my employment. I acknowledge that, unless otherwise agreed in a formal written employment agreement signed on behalf of the Company by an authorized officer, my employment with the Company is at will and therefore may be terminated by the Company or me at any time and for any reason.

15. **Survival and Assignment by the Company.** I understand that my obligations under this Agreement will continue in accordance with its express terms regardless of any changes in my title, position, duties, salary, compensation or benefits or other terms and conditions of employment. I further understand that my obligations under this Agreement will continue following the termination of my employment regardless of the manner of such termination and will be binding upon my heirs, executors and administrators. The Company will have the right to assign this Agreement to its affiliates, successors and assigns. I expressly consent to be bound by the provisions of this Agreement for the benefit of the Company or any parent, subsidiary or affiliate to whose employ I may be transferred without the necessity that this Agreement be resigned at the time of such transfer.

16. **Disclosure to Future Employers.** I will provide a copy of this Agreement to any prospective employer, partner or co-venturer prior to entering into an employment, partnership or other business relationship with such person or entity.

17. **Defend Trade Secrets Act Notice of Immunity Rights.** I acknowledge that the Company has provided me with the following notice of immunity rights in compliance with the requirements of the Defend Trade Secrets Act: (i) I shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of Proprietary Information that is made in confidence to a Federal, State, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, (ii) I shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of Proprietary Information that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal and (iii) if I file a lawsuit for retaliation by the Company for reporting a suspected violation of law, I may disclose the Proprietary Information to my attorney and use the Proprietary Information in the court proceeding, if I file any document containing the Proprietary Information under seal, and do not disclose the Proprietary Information, except pursuant to court order.

18. **Exit Interview.** If and when I depart from the Company, I may be required to attend an exit interview and sign an "Employee Exit Acknowledgement" to reaffirm my acceptance and acknowledgement of the obligations set forth in this Agreement. During the Restricted Period following termination of my employment, I will notify the Company of any change in my address and of each subsequent employment or business activity, including the name and address of my employer or other post-Company employment plans and the nature of my activities.

19. **Severability.** In case any provisions (or portions thereof) contained in this Agreement will, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect the other provisions of

this Agreement, and this Agreement will be construed as if such invalid, illegal or unenforceable provision had never been contained herein. If, moreover, any one or more of the provisions contained in this Agreement will for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it will be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it will then appear.

20. **Entire Agreement.** This Agreement constitutes the entire and only agreement between the Company and me respecting the subject matter hereof, and supersedes all prior agreements and understandings, oral or written, between us concerning such subject matter. No modification, amendment, waiver or termination of this Agreement or of any provision hereof will be binding unless made in writing and signed by an authorized officer of the Company. Failure of the Company to insist upon strict compliance with any of the terms, covenants or conditions hereof will not be deemed a waiver of such terms, covenants or conditions. In the event of any inconsistency between this Agreement and any other contract between the Company and me, the provisions of this Agreement will prevail.

21. **Interpretation.** This Agreement will be deemed to be made and entered into in the Commonwealth of Massachusetts, and will in all respects be interpreted, enforced and governed under the laws of the Commonwealth of Massachusetts. I hereby agree to consent to personal jurisdiction of the state and federal courts situated within Suffolk County, Massachusetts for purposes of enforcing this Agreement, and waive any objection that I might have to personal jurisdiction or venue in those courts. As used in this Agreement, "including" means "including but not limited to".



**BY SIGNING BELOW, I CERTIFY THAT I HAVE READ THIS AGREEMENT CAREFULLY AND AM SATISFIED THAT I UNDERSTAND IT COMPLETELY.**

IN WITNESS WHEREOF, the undersigned has executed this agreement as a sealed instrument as of the date set forth below.

Signed: \_\_\_\_\_  
(Employee's full name)

Type or print name: \_\_\_\_\_

Last four digits of SSN: \_\_\_\_\_

Date: \_\_\_\_\_

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**EXHIBIT A**

To: [ \_\_\_\_\_ ]

From: \_\_\_\_\_

Date: \_\_\_\_\_

SUBJECT: **Prior Inventions**

The following is a complete list of all inventions or improvements relevant to the subject matter of my employment by the Company that have been made or conceived or first reduced to practice by me alone or jointly with others prior to my engagement by the Company:

No inventions or improvements

See below:

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Additional sheets attached

The following is a list of all patents, patent applications and other patent rights that I invented:

None

See below:

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## CERTIFICATIONS

I, Eric D. Shaff, 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 9, 2020

By: /s/ Eric D. Shaff  
Eric D. Shaff  
President, Chief Executive Officer and Director

## CERTIFICATIONS

I, Marcus Chapman, 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 9, 2020

By: /s/ Marcus Chapman  
Marcus Chapman  
Senior Vice President, Finance and Principal Financial  
and Accounting Officer

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

(1) I, Eric D. Shaff, President and 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:

- (2) The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (3) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 9, 2020

/s/ Eric D. Shaff

Eric D. Shaff

President and Chief Executive Officer

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

I, Marcus Chapman, Senior Vice President, Finance and Principal Financial and Accounting 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, 2020 (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 9, 2020

/s/ Marcus Chapman

\_\_\_\_\_  
Marcus Chapman

Senior Vice President, Finance and Principal Financial and  
Accounting Officer