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, 2019

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)**	**27-4326290** **(I.R.S. Employer Identification No.)**
200 Sidney Street - 4th Floor **Cambridge, MA** **(Address of principal executive offices)**	**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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Small reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

As of October 29, 2019, the registrant had 69,993,952 shares of common stock, $0.001 par value per share, outstanding.

Seres Therapeutics, Inc.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or the Quarterly Report, contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, 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, 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;
- 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;
- the effect that the reduction in trial size for our ECOSPOR III trial will have on the results of the trial;
- 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.

PART I – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 49,296	$ 85,820
Investments	34,492	—
Prepaid expenses and other current assets	4,073	6,845
Accounts receivable	1,717	—
Total current assets	89,578	92,665
Property and equipment, net	21,160	26,294
Operating lease assets	11,899	—
Restricted investments	1,400	1,400
Restricted cash	114	113
Total assets	$ 124,151	$ 120,472
Liabilities and Stockholders’ Deficit		
Current liabilities:		
Accounts payable	$ 4,455	$ 6,415
Accrued expenses and other current liabilities	10,522	15,207
Operating lease liabilities	4,335	—
Deferred revenue - related party	21,135	20,419
Deferred revenue	1,790	—
Total current liabilities	42,237	42,041
Operating lease liabilities, net of current portion	16,844	—
Lease incentive obligation, net of current portion	—	6,776
Deferred rent	—	2,216
Deferred revenue, net of current portion - related party	94,215	116,840
Deferred revenue, net of current portion	2,410	—
Other long-term liabilities	664	644
Total liabilities	156,370	168,517
Commitments and contingencies (Note 12)		
Stockholders’ deficit:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2019 and December 31, 2018; no shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2019 and December 31, 2018; 69,993,952 and 40,936,735 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	70	41
Additional paid-in capital	408,575	341,284
Accumulated other comprehensive income	7	—
Accumulated deficit	(440,871)	(389,370)
Total stockholders’ deficit	(32,219)	(48,045)
Total liabilities and stockholders’ deficit	$ 124,151	$ 120,472

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,	
	2019	**2018**	**2019**	**2018**
Revenue:				
Collaboration revenue - related party	$ 4,840	$ 8,684	$ 21,909	$ 16,721
Grant revenue	85	371	791	917
Collaboration revenue	2,106	—	4,183	—
Total revenue	7,031	9,055	26,883	17,638
Operating expenses:				
Research and development expenses	18,317	23,675	59,109	71,188
General and administrative expenses	5,897	7,591	18,966	25,063
Restructuring expenses	—	—	1,492	—
Total operating expenses	24,214	31,266	79,567	96,251
Loss from operations	(17,183)	(22,211)	(52,684)	(78,613)
Other income (expense):				
Interest income (expense), net	335	262	744	958
Other income	439	—	439	—
Total other income (expense), net	774	262	1,183	958
Net loss	$ (16,409)	$ (21,949)	$ (51,501)	$ (77,655)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.23)	$ (0.54)	$ (0.99)	$ (1.91)
Weighted average common shares outstanding, basic and diluted	69,944,068	40,806,413	52,143,492	40,699,422
Net loss	(16,409)	(21,949)	(51,501)	(77,655)
Other comprehensive income:				
Unrealized gain on investments, net of tax of $0	$ 7	$ 20	$ 7	$ 137
Total other comprehensive income	7	20	7	137
Comprehensive loss	$ (16,402)	$ (21,929)	$ (51,494)	$ (77,518)

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 Loss	Total Stockholders' Equity (Deficit)
	Shares	Par Value				
Balance at December 31, 2017	40,571,015	$ 40	$ 324,376	$ (263,571)	$ (146)	$ 60,699
Issuance of common stock upon exercise of stock options	48,053	—	32	—	—	32
Issuance of common stock upon vesting of RSUs, net of tax withholdings	51,500	—	—	—	—	—
Repurchase of common stock for employee tax withholdings	(17,900)	—	(197)	—	—	(197)
Stock-based compensation expense	—	—	4,236	—	—	4,236
Unrealized gain on investments	—	—	—	—	40	40
Adoption of new revenue standard (ASC 606)	—	—	—	(26,857)	—	(26,857)
Net loss	—	—	—	(27,919)	—	(27,919)
Balance at March 31, 2018	40,652,668	$ 40	$ 328,447	$ (318,347)	$ (106)	$ 10,034
Issuance of common stock upon exercise of stock options	92,013	—	64	—	—	64
Issuance of common stock upon vesting of RSUs, net of tax withholdings	10,000	—	27	—	—	27
Stock-based compensation expense	—	—	4,334	—	—	4,334
Unrealized gain on investments	—	—	—	—	77	77
Net loss	—	—	—	(27,787)	—	(27,787)
Balance at June 30, 2018	40,754,681	$ 40	$ 332,872	$ (346,134)	$ (29)	$ (13,251)
Issuance of common stock upon exercise of stock options	56,442	—	40	—	—	40
Issuance of common stock under ESPP plan	33,332	—	257	—	—	257
Stock-based compensation expense	—	—	4,317	—	—	4,317
Unrealized gain on investments	—	—	—	—	21	21
Net loss	—	—	—	(21,949)	—	(21,949)
Balance at September 30, 2018	40,844,455	$ 40	$ 337,486	$ (368,083)	$ (8)	$ (30,565)

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Par Value	Paid-in Capital	Deficit	Other Comprehensive Income	Stockholders' Deficit
Balance at December 31, 2018	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)
Balance at March 31, 2019	41,094,832	$ 41	$ 343,829	$ (413,703)	$ —	$ (69,833)
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)
Balance at June 30, 2019	69,913,410	$ 70	$ 406,424	$ (424,462)	$ —	$ (17,968)
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)
Balance at September 30, 2019	69,993,952	$ 70	$ 408,575	$ (440,871)	$ 7	$ (32,219)

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, 2019	Nine Months Ended September 30, 2018
Cash flows from operating activities:		
Net loss	$ (51,501)	$ (77,655)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,199	12,887
Depreciation and amortization expense	5,803	5,869
Non-cash operating lease cost	1,683	—
Accretion of discount on investments	(87)	(199)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,772	(1,461)
Accounts receivable	(1,717)	—
Deferred revenue	(17,709)	(16,328)
Accounts payable	(1,857)	106
Operating lease liabilities	(3,164)	—
Accrued expenses and other current and long-term liabilities	(2,895)	1,261
Net cash (used in) operating activities	(62,473)	(75,520)
Cash flows from investing activities:		
Purchases of property and equipment	(772)	(2,133)
Purchases of investments	(34,407)	(21,832)
Sales and maturities of investments	8	118,887
Net cash (used in) provided by investing activities	(35,171)	94,922
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of commissions, underwriting discounts and offering costs	60,527	—
Proceeds from exercise of stock options	145	136
Proceeds from issuance of common stock and restricted common stock	153	26
Payments of employee tax obligations related to vesting of restricted stock units	—	(196)
Issuance of common stock under ESPP plan	296	257
Net cash provided by (used in) financing activities	61,121	223
Net increase (decrease) in cash and cash equivalents	(36,523)	19,625
Cash, cash equivalents and restricted cash at beginning of period	85,933	37,601
Cash, cash equivalents and restricted cash at end of period	$ 49,410	$ 57,226
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment purchases included in accounts payable and accrued expenses	$ 54	$ 242
Reduction of right-of-use assets and lease liability from operating lease modifications or reassessments	154	—

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

1. Nature of the Business and Basis of Presentation

Seres Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Delaware in October 2010 under the name Newco LS21, Inc. In October 2011, the Company changed its name to Seres Health, Inc., and in May 2015, the Company changed its name to Seres Therapeutics, Inc. The Company is a microbiome therapeutics platform company developing a novel class of biological drugs, which are designed to treat disease by restoring the function of a dysbiotic microbiome. The Company is developing SER-287 to treat ulcerative colitis ("UC"), a form of inflammatory bowel disease ("IBD"). SER-109 is designed to reduce recurrences of *Clostridium difficile*, or *C. 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, which, if approved by the U.S. Food and Drug Administration ("FDA"), could be a first-in-field oral microbiome drug. In addition, using its microbiome therapeutics platform, the Company is developing product candidates to treat diseases where the microbiome is implicated, including SER-301, a rationally designed, fermented IBD candidate, and SER-401, a microbiome therapeutic candidate for use with checkpoint inhibitors in patients with metastatic melanoma. Supporting the Company's research and development efforts are its deep capabilities related to microbiome therapeutic drug discovery, manufacturing, quality, and clinical development. The Company believes that these capabilities provide it with important competitive advantages related to the advancement of this novel treatment modality.

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.

In February 2019, the Company implemented corporate changes to focus its resources on advancing its clinical-stage therapeutic candidates. As a result, the Company is concentrating on completing the SER-287 Phase 2b study in mild-to-moderate UC, obtaining results from the ongoing SER-109 Phase 3 study for recurrent CDI, advancing the SER-401 Phase 1b study, in collaboration with the Parker Institute for Cancer Immunotherapy and MD Anderson Cancer Center, 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 therapeutic candidates, the Company made changes to its management team and reduced headcount by approximately 30 percent.

On June 18, 2019, the Company completed an underwritten public offering, in which the Company sold 26,666,667 shares of its common stock at a price to the public of $2.25 per share. The aggregate net proceeds received by the Company from the offering were approximately $55,976, after deducting underwriting discounts and commissions and offering expenses payable by the Company. In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 2,666,666 shares of common stock at the public offering price, less underwriting discounts and commissions. On June 21, 2019, the Company sold an additional 2,151,911 shares of its common stock at a price to the public of $2.25 per share. The aggregate net proceeds received by the Company were approximately $4,551, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. The Company has experienced negative cash flows and had an accumulated deficit of $440,871 and $389,370 as of September 30, 2019 and December 31, 2018, respectively. For the nine months ended September 30, 2019, the Company incurred a loss of $51,501 and used $62,473 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 investments at September 30, 2019 of $83,788 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”), a significant stockholder 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, 2019 and for the three and nine months ended September 30, 2019 and 2018 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, 2018 included in the Company’s annual report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the SEC on March 6, 2019 (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, 2018 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, 2019 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2019.

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, 2018, 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, 2019 except for the adoption of the new lease accounting standard discussed in Note 9, *Leases.*

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. 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:

	Three and Nine Months Ended September 30,	
	2019	**2018**
Stock options to purchase common stock	8,258,031	7,444,040
Unvested restricted stock units	145,900	289,908
Shares issuable under ESPP	13,171	44
Total common stock equivalents	8,417,102	7,733,992

Leases

The Company evaluates arrangements at inception to determine if an arrangement is or contains a lease. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company uses an incremental borrowing rate that the Company would expect to incur for a fully collateralized loan over a similar term under similar economic conditions to determine the present value of the lease payments. The lease payments used to determine the Company's operating lease assets may include lease incentives and stated rent increases and are recognized in the Company's operating lease assets in the Company's condensed consolidated balance sheets. Lease expense for operating lease payments is recognized on a straight-line basis over the term of the lease. Variable lease payments are recognized as the associated obligation is incurred.

Restructuring

Restructuring costs are comprised of severance costs related to workforce reductions. The Company recognizes restructuring charges when the liability is incurred. Employee termination benefits are accrued at the date management has committed to a plan of termination and employees have been notified of their termination dates and expected severance payments.

Recently Issued Accounting Standards

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, ("Topic 842"), which establishes principles that lessees and lessors shall apply to report useful information to users of financial statements about the amount, timing and uncertainty of cash flows arising from a lease. The most notable change is lessees recognizing an asset and liability on their balance sheet for operating leases. In 2018, the FASB issued ASU 2018-01, and ASU 2018-11, which collectively adds two practical expedients, provides a second modified retrospective transition method which does not require retrospective adjustment of prior periods, and provides certain narrow scope improvements to the new lease guidance. ASU 2016-02 and the amending ASUs are effective for the Company for annual periods beginning after December 15, 2018 and interim periods therein, with early adoption permitted.

The Company adopted the new guidance as of January 1, 2019 using the modified retrospective transition approach with no restatement of prior periods or cumulative adjustment to accumulated deficit. Upon adoption, the Company elected the package of transition practical expedients, which allowed the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. The Company also made an accounting policy election not to recognize leases with an initial term of 12 months or less within its condensed consolidated balance sheets and to recognize those lease payments on a straight-line basis in its condensed consolidated statements of operations and comprehensive loss over the lease term. Upon adoption of the new leasing standards, the Company recognized an operating lease asset of approximately $13,737 and a corresponding operating lease liability of approximately $24,497, which are included in the Company's condensed consolidated balance sheet. The adoption of the new leasing standards did not have any impact on the Company's condensed consolidated statements of operations and comprehensive loss. The impact to the Condensed Consolidated Balance Sheets for the opening balances is as follows (in thousands):

	December 31, 2018	Impact of adoption of ASC 842	January 1, 2019
Operating lease assets	$ —	$ 13,737	$ 13,737
Accrued expenses and other current liabilities	15,207	(1,768)	13,439
Operating lease liabilities	—	4,285	4,285
Lease incentive obligation, net of current portion	6,776	(6,776)	—
Deferred rent	2,216	(2,216)	—
Operating lease liabilities, net of current portion	—	20,212	20,212

In June 2018, the FASB issued ASU 2018-07, "*Compensation – Stock Compensation* (Topic 718)" ("ASU 2018-07"). ASU 2018-07 simplifies the accounting for nonemployee share-based payment transactions. This ASU is effective for public entities for interim and annual reporting periods beginning after December 15, 2018. The Company adopted the ASU effective January 1, 2019, the impact of adoption of this standard was immaterial to the Company's condensed consolidated financial statements.

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 eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. ASU 2018-13 is effective for annual reporting periods beginning after December 15, 2019 and interim periods within those annual periods and early adoption is permitted. The Company is currently evaluating the impact of its adoption of ASU 2018-13 on its condensed consolidated financial statements.

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
- Requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting that transaction together with revenue recognized under ASC 606 is precluded if the collaborative arrangement participant is not a customer.

This standard will be effective on January 1, 2020; however, early adoption is permitted. A retrospective transition approach is required for either all contracts or only for contracts that are not completed at the date of initial application of ASC 606, with a cumulative adjustment to opening retained earnings. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial position and results of operations.

3. Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and investments are carried at fair value, determined according to the fair value hierarchy described above. The money market funds represent open-ended mutual funds with published daily net asset values at which investors can freely subscribe to or redeem from the funds and is classified as Level 1 in the fair value hierarchy. The carrying values of the Company's cash, accounts receivable, other current assets, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities. During the nine months ended September 30, 2019, there were no transfers between Level 1 and Level 2 financial assets.

The following table presents information about the Company's assets as of September 30, 2019 and December 31, 2018 that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (note there were no liabilities measured at fair value on a recurring basis as of September 30, 2019 or December 31, 2018):

	Fair Value Measurements as of September 30, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 24,134	$ —	$ —	$ 24,134
Commercial paper	—	$ 5,495	—	5,495
Investments:				
Commercial paper	$ —	$ 17,920	$ —	$ 17,920
Corporate bonds	—	15,029	—	15,029
Government securities	—	545	—	545
Treasury bonds	—	998	—	998
	$ 24,134	$ 39,987	$ —	$ 64,121

	Fair Value Measurements as of December 31, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 39,982	$ —	$ —	$ 39,982
	$ 39,982	$ —	$ —	$ 39,982

As of September 30, 2019 and December 31, 2018 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

As of September 30, 2019 the fair value of available-for-sale investments by type of security was as follows:

	September 30, 2019			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Investments:				
Commercial paper	$ 17,920	$ —	$ —	$ 17,920
Corporate bonds	15,023	6	—	15,029
Government securities	545	—	—	545
Treasury bonds	997	1	—	998
	$ 34,485	$ 7	$ —	$ 34,492

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.

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2019	December 31, 2018
Laboratory equipment	$ 15,078	$ 14,695
Computer equipment	2,874	2,864
Furniture and office equipment	1,033	1,033
Leasehold improvements	27,977	27,977
Construction in progress	140	26
	47,102	46,595
Less: Accumulated depreciation and amortization	$ (25,942)	$ (20,301)
	$ 21,160	$ 26,294

Depreciation and amortization expense was $1,876, $5,803, $1,974, and $5,869 for the three and nine months ended September 30, 2019 and 2018, respectively.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2019	December 31, 2018
Development and manufacturing costs	$ 5,537	$ 7,046
Payroll and payroll-related costs	3,564	5,020
Facility and other	1,421	3,141
	$ 10,522	$ 15,207

7. Stockholders' Deficit Common Stock

Stock Options

The following table summarizes the Company's stock option activity since December 31, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	7,561,719	$ 12.26	$ 7.23	$ 4,958
Granted	2,346,350	5.90		
Exercised	(90,125)	1.61		
Forfeited	(1,559,913)	12.69		
Outstanding as of September 30, 2019	8,258,031	$ 10.49	$ 7.21	$ 4,230
Options vested and expected to vest as of September 30, 2019	8,258,031	10.49	7.21	4,230
Options exercisable as of September 30, 2019	4,641,642	$ 12.49	5.94	$ 4,028

The weighted average grant-date fair value of stock options granted during the three and nine months ended September 30, 2019 and 2018 was $2.12, $4.24, $5.67 and $6.83 per share, respectively.

During the nine months ended September 30, 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, 2019, 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, 2019, the Company did not record any expense for these stock options from the dates of issuance through September 30, 2019.

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, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2018	226,900	$ 9.64
Granted	15,000	2.29
Forfeited	(22,500)	8.77
Vested	(73,500)	9.98
Unvested restricted stock units as of September 30, 2019	145,900	$ 8.85

Stock-based Compensation Expense

The Company recorded stock-based compensation expense related to stock options, restricted stock units and the Company's Employee Stock Purchase Plan ("ESPP") in the following expense categories of its condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development expenses	$ 1,033	$ 2,246	$ 3,574	$ 6,436
General and administrative expenses	1,004	2,071	2,625	6,451
	$ 2,037	$ 4,317	$ 6,199	$ 12,887

Employee Stock Purchase Plan

The ESPP provides that eligible employees may contribute up to 15% of their eligible earnings toward the semi-annual purchase of the Company's common stock. The ESPP is qualified under Section 423 of the Internal Revenue Code. The employee's purchase price is derived from a formula based on the closing price of the common stock on the first day of the offering period versus the closing price on the date of purchase (or, if not a trading day, on the immediately preceding trading day). The offering period under the ESPP has a duration of six months, and the purchase price with respect to each offering period beginning on or after such date is, until otherwise amended, equal to 85% of the lesser of (i) the fair market value of the Company's common stock at the commencement of the applicable six-month offering period or (ii) the fair market value of the Company's common stock on the purchase date. The Company recorded an immaterial amount of stock-based compensation expense under the ESPP for the three and nine months ended September 30, 2019.

The total number of available ESPP shares is increased annually, which began in 2016 and will end in 2025. The ESPP allows for share replenishment equal to the lesser of (i) 400,000 shares and (ii) 1% of the number of shares of the Company’s common stock outstanding on the last day of the preceding calendar year, or an amount determined by the board of directors. As of September 30, 2019, a total of 1.8 million shares were reserved and available for issuance under the ESPP.

8. 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 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. The transaction price as of September 30, 2019 was approximately $190,000.

In April 2019, the Company, with the approval of the Seres/NHS Joint Steering Committee, as provided for in the License Agreement, modified the SER-109 clinical trial. As a result of this modification, the Company and NHS agreed, and informed the FDA, that the target study enrollment would be reduced from 320 subjects to 188 subjects. This modification to the SER-109 clinical trial constituted a contract modification under ASC 606. The Company accounted for the contract modification through a cumulative catch-up adjustment because the contract modification did not add any additional goods or services and the remaining goods and services are not distinct. The modification reduced the total estimated costs in the Company's cost-to-cost model for the License Agreement and resulted in the Company recognizing $6,830 of collaboration revenue – related party in the three and six months ended June 30, 2019.

During the three and nine months ended September 30, 2019 and 2018, using the cost-to-cost method, which best depicts the transfer of control to the customer, the Company recognized $4,840, $21,909, $8,684 and $16,721 of Collaboration revenue – related party, respectively.

As of September 30, 2019 and December 31, 2018, there was $115,350, and $137,259, respectively, of deferred revenue related to the unsatisfied portion of the performance obligation under the License Agreement. As of September 30, 2019, the deferred revenue is classified as current or non-current in the 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, and the second and third of which become due on January 2, 2020 and January 4, 2021, respectively. 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.

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

As of September 30, 2019, there was $4,200 of deferred revenue associated with the Research Agreement, with $1,790 presented as current and $2,410 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 assets and contract liabilities during the nine months ended September 30, 2019 and 2018:

	Balance as of December 31, 2018	Additions	Deductions	Balance as of September 30, 2019
Nine months ended September 30, 2019				
Contract liabilities:				
Deferred revenue - related party	137,259	—	(21,909)	115,350
Deferred revenue	—	8,383	(4,183)	4,200

	Balance as of January 1, 2018	Additions	Deductions	Balance as of September 30, 2018
Nine months ended September 30, 2018				
Contract liabilities:				
Deferred revenue - related party	123,783	393	(16,721)	107,455

During the three and nine months ended September 30, 2019 and 2018 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,	
	2019	2018	2019	2018
Revenue recognized in the period from:				
Amounts included in the contract liability at the beginning of the period	6,081	8,684	21,909	16,721

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.

9. Leases

The Company leases real estate, primarily laboratory, office and manufacturing space. The Company's leases have remaining terms ranging from less than 1 year to 5 years. Certain leases include one or more options to renew, exercised at the Company's sole discretion, with renewal terms that can extend the lease from one year to five years. The Company evaluated the renewal options in its leases to determine if it was reasonably certain that the renewal option would be exercised, and therefore should be included in the calculation of the operating lease assets and operating lease liabilities. Given the Company's current business structure, uncertainty of future growth, and the associated impact to real estate, the Company concluded that it is not reasonably certain that any renewal options would be exercised. Therefore, the operating lease assets and lease liabilities only contemplate the initial lease terms. All of the Company's leases qualify as operating leases.

In July 2019, the Company entered into a sublease agreement with a related party to sublease a portion of its office and laboratory space in Cambridge, Massachusetts (see Note 13). The term of the sublease agreement commenced in July 2019 and ends on the last day of the 24^{th} calendar month following commencement, with no option to extend. The annual rent for the subleased premises will be approximately \$1,200 in the first year and \$1,300 in the second year, which is greater than the annual rent owed by the Company to the landlord for the leased premises. The sublessee is obligated to pay all real estate taxes and costs related to the subleased premises, including cost of operations, maintenance, repair, replacement and property management.

As of September 30, 2019, future undiscounted cash inflows under the sublease are as follows:

Year Ending December 31,	
2019 (remaining 3 months)	$ 307
2020	1,248
2021	633
	$ 2,188

The Company concluded that the sublease is an operating lease. Consistent with the Company's policy election for lessor operating leases, each lease component and its associated non-lease components is accounted for as a single lease component.

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

	As of September 30, 2019
Assets:	
Operating lease assets	$ 11,899
Liabilities:	
Operating lease liabilities	$ 4,335
Operating lease liabilities, net of current portion	16,844
Total operating lease liabilities	$ 21,179

The following table summarizes the effect of lease costs in the Company's condensed consolidated statement of operations and comprehensive loss:

	For the Three Months Ended September 30, 2019	For the Nine Months Ended September 30, 2019
Operating lease costs	$ 1,148	$ 3,456
Short-term lease costs	330	1,547
Variable lease costs	716	2,302
Sublease income	(439)	(439)
Total lease costs	$ 1,755	$ 6,866

During the three and nine months ended September 30, 2019, the Company recognized $1,096 and $3,299 of rental expense related to office, laboratory, and manufacturing space. During the three and nine months ended September 30, 2019, the Company made cash payments of $1,647 and $4,935 for operating leases, respectively.

The minimum lease payments for the next five years and thereafter is expected to be as follows (in thousands):

	As of September 30, 2019
2019 (remaining 3 months)	$ 1,578
2020	6,302
2021	6,461
2022	6,390
2023	5,158
2024 and thereafter	—
Total future minimum lease payments	$ 25,889
Less: interest	(4,710)
Present value of operating lease liabilities	$ 21,179

As of September 30, 2019, the weighted average remaining lease term was 4.12 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 11%.

ASC 840 Disclosures

The future minimum lease payments under the Company's operating leases as of December 31, 2018, were as follows (in thousands):

	As of December 31, 2018
2019	$ 6,342
2020	6,120
2021	6,221
2022	6,372
2023	5,158
2024 and thereafter	—
Total future minimum lease payments	$ 30,213

During the three and nine months ended September 30, 2018, the Company recognized $1,093 and $3,299 of rental expense, respectively, related to office, laboratory, and manufacturing space.

10. 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 is concentrating on completing the SER-287 Phase 2b study in mild-to-moderate UC, obtaining results from the ongoing SER-109 Phase 3 study for recurrent CDI, advancing the SER-401 Phase 1b study, in collaboration with the Parker Institute for Cancer Immunotherapy and MD Anderson Cancer Center, 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 therapeutic candidates, the Company made changes to its management team and reduced headcount by approximately 30 percent.

During the nine months ended September 30, 2019 the Company recorded charges of $1,492, related to severance and other termination benefits. No restructuring charges were recorded during the three months ended September 30, 2019.During the three and nine months ended September 30, 2019 the Company paid $206 and $1,101, respectively, and it expects to pay approximately $391 in the remainder of 2019.

The outstanding restructuring liabilities are included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. As of September 30, 2019, the components of the liabilities were as follows:

	Employee Severance and Other Benefits
Restructuring expenses	$ 1,492
Cash payments	$ (1,101)
Liability included in accrued expenses and other current liabilities at September 30, 2019	$ 391

11. Income Taxes

The Company did not provide for any income taxes for the three and nine months ended September 30, 2019 and 2018.

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, 2019 and December 31, 2018. Management reevaluates the positive and negative evidence at each reporting period.

As of September 30, 2019 and December 31, 2018, 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. There are no currently ongoing or pending examinations in any jurisdictions.

12. Commitments and Contingencies

Leases

Refer to Note 9, *Leases*, for discussion of the commitments associated with the Company's lease portfolio.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of September 30, 2019 or December 31, 2018.

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, 2019 or December 31, 2018.

13. Related Party Transactions

As described in Note 8, 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, 2019 and 2018, the Company recognized $4,840, $21,909, $8,684 and $16,721 of related party revenue associated with the License Agreement, respectively. As of September 30, 2019, there was $115,350 of deferred revenue related to the License Agreement, which is classified as current or non-current in the consolidated balance sheets. The Company has made no payments to NHS during the three and nine months ended September 30, 2019 and 2018. There is no amount due from NHS as of September 30, 2019.

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 24th calendar month following commencement, with no option to extend (see Note 9). Under this agreement, the Company recorded other income of $439 during the three and nine months ended September 30, 2019. The Company received cash payments of $409 during the three and nine months ended September 30, 2019

14. Subsequent Events

In October 2019, the Company entered into a loan and security 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. The Company received the first tranche of $25,000 at the closing on October 29, 2019. Upon satisfaction of certain milestones, the second tranche will be available and will allow the Company to borrow an additional amount up to $12,500 through March 15, 2021. 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. The Company received $24,575 upon closing, net of $425 of closing costs.

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, 2019, 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 platform company developing a novel class of biological drugs, which are designed to treat disease by restoring the function of a dysbiotic microbiome. SER-287 is being developed to treat ulcerative colitis, or UC. SER-109 is designed to reduce recurrences of 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 and, if approved by the U.S. Food and Drug Administration, or FDA, could be a first-in-field oral microbiome drug. In addition, using our microbiome therapeutics platform, we are developing product candidates to treat diseases where the microbiome is implicated, including SER-301, a rationally designed, fermented inflammatory bowel disease, or IBD, candidate, and SER-401, a microbiome therapeutic candidate for use with checkpoint inhibitors in patients with metastatic melanoma. 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-287, SER-109 and SER-401 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 $51.5 million for the nine months ended September 30, 2019. As of September 30, 2019, we had an accumulated deficit of $440.9 million and cash, cash equivalents and investments totaling $83.8 million.

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 completing our SER-287 Phase 2b study in mild-to-moderate UC patients, obtaining results from our ongoing SER-109 Phase 3 study for the treatment of recurrent CDI, advancing our SER-401 Phase 1b study, in collaboration with the Parker Institute for Cancer Immunotherapy, or PICI and MD Anderson Cancer Center, or 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 therapeutic candidates, we made changes to our management team and reduced headcount by approximately 30 percent.

In March 2019, we entered into a Research and Collaboration and Option Agreement, or the Research Agreement, with MedImmune, LLC, a wholly owned subsidiary of AstraZeneca Inc., or AstraZeneca. Pursuant to the Research Agreement, we and AstraZeneca agreed to conduct certain research and development activities 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. AstraZeneca has agreed to bear all costs of conducting its activities under the Research Agreement and to reimburse us for certain costs incurred under the Research Agreement. Additionally, AstraZeneca has agreed pay to us a total of $20.0 million in three equal installments, the first of which we received in April 2019, and the second and third of which become due in January 2020 and January 2021. We granted AstraZeneca the exclusive option to negotiate certain exclusive license rights. If AstraZeneca exercises an 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 June 2019, we completed an underwritten public offering, in which we sold 26,666,667 shares of our common stock at a price to the public of $2.25 per share. We received aggregate net proceeds from the offering of approximately $56.0 million, after deducting underwriting discounts and commissions and offering expenses payable by us. In addition, we granted the underwriters a 30-day option to purchase up to an additional 2,666,666 shares of common stock at the public offering price, less underwriting discounts and commissions. In June 2019, we sold an additional 2,151,911 shares of our common stock at a price to the public of $2.25 per share. We received net proceeds of approximately $4.6 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

In October 2019, we entered into a loan and security agreement with Hercules Capital, Inc., or Hercules, pursuant to which a term loan in an aggregate principal amount up to $50.0 million, or the Term Loan Facility, is available to us in three tranches. We received $24.6 million, net of $0.4 million of closing costs, upon signing the agreement on October 29, 2019 and, subject to certain conditions, two additional tranches of $12.5 million each will be available to us. See "—Liquidity and Capital Resources."

SER-287

SER-287 is an oral, donor-derived 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 to evaluate SER-287 in approximately 201 patients with mild-to-moderate UC. Two groups of patients will receive 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 Biologics License Application, or BLA, to be submitted for SER-287 for the treatment of UC. We expect to report top-line data in the second half of 2020.

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.

We believe that our continued development of SER-287 is supported by our Phase 1b clinical study of SER-287 in patients with mild-to-moderate UC in which we observed a beneficial impact on clinical remission and endoscopic improvement and various markers of SER-287 biological activity, including microbiome engraftment, detection of metabolomic markers, and biopsy transcriptional signals correlating with the clinical trial results. Of the 11 patients treated with SER-287 who achieved clinical remission in the Phase 1b clinical study, preliminary data showed that no patients experienced a disease flare in the 26 weeks following the end of treatment, which we believe is suggestive of a possible longer-term treatment effect. Additionally, there was no imbalance of adverse events between the treatment arm and placebo, the most common being gastrointestinal related, and no serious adverse events observed in the Phase 1b clinical study.

SER-109

SER-109 is an oral, donor-derived microbiome therapeutic candidate designed to restore the depleted, or dysbiotic, gastrointestinal microbiome of patients with recurrent CDI. SER-109 has been granted Breakthrough Therapy Designation and Orphan Drug Designation for the treatment of recurrent CDI.

We have been enrolling a 320 patient, placebo-controlled SER-109 Phase 3 study, ECOSPOR III, in patients with recurrent CDI. All patients entering ECOSPOR III have tested positive for *C. difficile* toxin. This inclusion criterion was implemented to ensure enrollment of only patients with active CDI. The original 320 patient trial was designed to evaluate SER-109 efficacy and develop a comprehensive safety database, in order to potentially serve as a single study supporting registration. Consistent with our recent actions to drive toward obtaining validating near-term clinical data, a revised ECOSPOR III study design has been implemented reducing the size of the study to 188 patients. The size and powering calculations of the modified study are informed by prior SER-109 study results, published CDI trial data utilizing toxin testing, and preliminary blinded and open label CDI recurrence rate data from the ongoing ECOSPOR III study.

In previous communications with the FDA regarding a potential reduction in ECOSPOR III study size, the agency indicated that if the statistical significance of the outcome of the study is insufficient for product registration, we may be required to obtain additional confirmatory evidence of efficacy, such as a second Phase 3 study. Reducing the study size may also require additional patient exposure to further establish safety. We believe ECOSPOR III is designed to provide statistically rigorous efficacy data. We expect to report top-line data in mid-2020.

SER-401

SER-401 is an oral 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. We expect preliminary results in the second half of 2020.

SER-301

We are also advancing our next generation, rationally-designed, fermented microbiome drug discovery capabilities, focusing on advancing SER-301, a preclinical-stage therapeutic candidate for UC. We have finalized the composition for SER-301, a preclinical therapeutic candidate for UC. The bacterial strains included in SER-301 were informed by our human clinical study results as well as preclinical mechanistic studies. We expect to initiate clinical development of SER-301 in early 2020. In connection with the SER-301 phase 1 study, we are entitled to receive a $10.0 million milestone payment under our collaboration with Nestec Ltd.

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:

- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC;
- continue the clinical development of SER-109 in our Phase 3 clinical study for the prevention of recurrent CDI;
- 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-301 for the treatment of UC;
- make strategic investments in manufacturing 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. 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 15 active patent application families, which includes 8 nationalized applications and 1 pending US provisional applications. 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,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Microbiome therapeutics platform	$ 11,558	$ 16,246	$ 39,707	$ 46,868
SER-109	2,313	3,956	7,174	14,829
SER-287	4,430	2,918	12,105	7,168
SER-262	16	555	123	2,323
Total research and development expenses	$ 18,317	$ 23,675	$ 59,109	$ 71,188

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 advance the clinical development of SER-287, conduct our ECOSPOR III Phase 3 clinical study of SER-109, continue to discover and develop additional product candidates, including SER-401 and SER-301 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 if 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 completing our SER-287 Phase 2b study in mild-to-moderate UC patients, obtaining results from the ongoing SER-109 Phase 3 study for recurrent CDI, 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

Other income (expense), net consists of interest earned on our cash, cash equivalents and investments and 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, 2019 or 2018.

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, 2018, filed with the SEC on March 6, 2019, 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, 2019 except for the adoption of the new leasing standard discussed in Note 9 to our Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report.

Results of Operations

Comparison of Three Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Change
	(in thousands)		
Revenue:			
Collaboration revenue - related party	$ 4,840	$ 8,684	$ (3,844)
Grant revenue	85	371	(286)
Collaboration revenue	2,106	—	2,106
Total revenue	7,031	9,055	(2,024)
Operating expenses:			
Research and development	18,317	23,675	(5,358)
General and administrative	5,897	7,591	(1,694)
Total operating expenses	24,214	31,266	(7,052)
Loss from operations	(17,183)	(22,211)	5,028
Other income (expense):			
Interest income (expense), net	335	262	73
Other income	439	—	439
Total other income (expense), net	774	262	512
Net loss	$ (16,409)	$ (21,949)	$ 5,540

Revenue

Total revenue was $7.0 million and $9.1 million for the three months ended September 30, 2019 and 2018, respectively. The revenue for the three months ended September 30, 2019 relates primarily to $4.8 million recognized under the License Agreement and $2.1 million recognized under the Research Agreement. The revenue for the three months ended September 30, 2018 principally relates to the recognition of amounts received under the License Agreement. The decrease is mainly due to a cumulative catch-up adjustment recorded during the three months ended September 30, 2018 related to a $20.0 million milestone being included in the transaction price. No similar event occurred during the three months ended September 30, 2019.

Research and Development Expenses

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Change
		(in thousands)	
Microbiome therapeutics platform	$ 11,558	$ 16,246	$ (4,688)
SER-109	2,313	3,956	(1,643)
SER-287	4,430	2,918	1,512
SER-262	16	555	(539)
Total research and development expenses	$ 18,317	$ 23,675	$ (5,358)

Research and development expenses were $18.3 million for the three months ended September 30, 2019, compared to $23.7 million for the three months ended September 30, 2018. The decrease of $5.4 million was due primarily to the following:

- a decrease of $4.7 million in research expenses related to our microbiome therapeutics platform, due primarily to a decrease in employee related costs of $3.0 million, a decrease in consulting related expenses of $1.0 million, and a decrease in professional fees of $0.4 million;
- a decrease of $1.6 million in expenses related to our SER-109 program due primarily to a decrease in contract manufacturing costs of $0.9 million, a decrease in clinical trial costs of $0.1 million, a decrease in sequencing expenses of $0.2 million, a decrease in lab consumables of $0.2 million and decrease in consulting related expenses of $0.1 million;
- an increase of $1.5 million in expenses for our SER-287 program due primarily to an increase of $1.5 million in clinical trials consulting expenses and an increase in contract manufacturing costs of $0.7 million; these increases were partially offset by a decrease in facilities expenses of $0.3 million, a decrease in sequencing costs of $0.2 million and a decrease in consultant related expenses of $0.2 million; and
- a decrease of $0.5 million in expenses for our SER-262 program due primarily to a decrease in clinical trials consulting expense.

General and Administrative Expenses

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$ 2,103	$ 3,768	$ (1,665)
Professional fees	2,406	1,606	800
Facility-related and other	1,388	2,217	(829)
Total general and administrative expenses	$ 5,897	$ 7,591	$ (1,694)

General and administrative expenses were $5.9 million for the three months ended September 30, 2019, compared to $7.6 million for the three months ended September 30, 2018. The decrease of $1.7 million was primarily due to the following:

- a decrease in personnel related costs of $1.7 million primarily related to a decrease stock compensation expense of $1.1 million and a decrease in payroll expenses of $0.7 million;
- an increase in professional fees of $0.8 million is primarily due to an increase in consultant related expenses; and
- a decrease in facility-related and other costs of $0.8 million primarily due to a decrease in IT-related expenses.

Other Income (Expense), Net

Other income (expense), net for the three months ended September 30, 2019 and 2018 was $0.8 million and $0.3 million, respectively, and is primarily due to sublease income of $0.4 million and interest income earned on our cash, cash equivalents and investments of $0.3 million.

Comparison of Nine Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Change
	(in thousands)		
Revenue:			
Collaboration revenue - related party	$ 21,909	$ 16,721	$ 5,188
Grant revenue	791	917	$ (126)
Collaboration revenue	4,183	—	4,183
Total revenue	26,883	17,638	9,245
Operating expenses:			
Research and development	59,109	71,188	(12,079)
General and administrative	18,966	25,063	(6,097)
Restructuring expenses	1,492	—	1,492
Total operating expenses	79,567	96,251	(16,684)
Loss from operations	(52,684)	(78,613)	25,929
Other income (expense):			
Interest income (expense), net	744	958	(214)
Other income	439	—	439
Total other income (expense), net	1,183	958	225
Net loss	$ (51,501)	$ (77,655)	$ 26,154

Revenue

Total revenue was $26.9 million and $17.6 million for the nine months ended September 30, 2019 and 2018, respectively. The revenue for the nine months ended September 30, 2019 relates primarily to amounts recognized under the License Agreement and the Research Agreement. The revenue for the nine months ended September 30, 2018 principally relates to the recognition of amounts received under the License Agreement. The increase is mainly due to the modification of our SER-109 Phase 3 trial which was accounted for through a cumulative catch-up adjustment because the contract modification did not add any additional goods or services and the remaining goods and services are not distinct. The modification reduced the total estimated costs in our cost-to-cost model for the License Agreement and resulted in the recognition of approximately $6.8 million in revenue in the nine months ended September 30, 2019. We also recognized $4.2 million in revenue in the nine months ended September 30, 2019 in connection with the Research Agreement.

Research and Development Expenses

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Change
	(in thousands)		
Microbiome therapeutics platform	$ 39,707	$ 46,868	$ (7,161)
SER-109	7,174	14,829	(7,655)
SER-287	12,105	7,168	4,937
SER-262	123	2,323	(2,200)
Total research and development expenses	$ 59,109	$ 71,188	$ (12,079)

Research and development expenses were $59.1 million for the nine months ended September 30, 2019, compared to $71.2 million for the nine months ended September 30, 2018. The decrease of $12.1 million was due primarily to the following:

- a decrease of $7.2 million in research expenses related to our microbiome therapeutics platform, due primarily to a decrease in employee and consultant related expenses of $7.7 million, and a decrease in sponsorships of $0.6 million; this was partially offset by an increase in facility related expenses of $1.0 million;
- a decrease of $7.7 million in expenses related to our SER-109 program due primarily to a decrease in clinical trial consulting expenses of $3.4 million, a decrease in contract manufacturing costs of $2.6 million, a decrease in facility related expenses of $0.8 million, a decrease in sequencing costs of $0.7 million and a decrease in employee related expenses of $0.1 million;

- an increase of $4.9 million in expenses for our SER-287 program due primarily to an increase in clinical trial consulting expenses of $4.3 million and an increase in contract manufacturing costs of $2.5 million; these increases were partially offset by a decrease in sequencing costs of $0.8 million, a decrease in lab consumables of $0.8 million, and a decrease in employee related expenses of $0.3 million; and
- a decrease of $2.2 million in expenses for our SER-262 program due primarily to a decrease in clinical trial consulting expenses of $1.8 million and a decrease in sequencing costs of $0.3 million.

General and Administrative Expenses

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 7,485	$ 12,379	$ (4,894)
Professional fees	6,883	5,713	1,170
Facility-related and other	4,598	6,971	(2,373)
Total general and administrative expenses	$ 18,966	$ 25,063	$ (6,097)

General and administrative expenses were $19.0 million for the nine months ended September 30, 2019, compared to $25.1 million for the nine months ended September 30, 2018. The decrease of $6.1 million was primarily due to the following:

- a decrease in personnel related costs of $4.9 million primarily related to a decrease in stock compensation expense of $3.8 million and a decrease in payroll related expenses of $0.5 million;
- an increase in professional fees of $1.2 million due to consulting related expenses; and
- a decrease in facility-related and other costs of $2.4 million primarily due to a decrease in IT-related expenses.

Restructuring

During the nine months ended September 30, 2019 we recorded charges of $1.5 million related to severance and other termination benefits. We paid $1.1 million during the nine months ended September 30, 2019 and expect to pay approximately $0.4 million in the remaining three months of 2019.

Other Income (Expense), Net

Other income (expense), net for the nine months ended September 30, 2019 and 2018 was $1.2 million and $1.0 million, respectively, and is primarily due to sublease income of $0.4 million and is partially offset by interest expense on our cash, cash equivalents and investments of $0.7 million.

Liquidity and Capital Resources

In June 2019, we completed an underwritten public offering, in which we sold 26,666,667 shares of our common stock at a price to the public of $2.25 per share. We received aggregate net proceeds from the offering of approximately $56.0 million, after deducting underwriting discounts and commissions and offering expenses payable by us. In addition, we granted the underwriters a 30-day option to purchase up to an additional 2,666,666 shares of common stock at the public offering price, less underwriting discounts and commissions. In June 2019, we sold an additional 2,151,911 shares of our common stock at a price to the public of $2.25 per share. We received net proceeds of approximately $4.6 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

In October 2019, we entered into a loan and security agreement with Hercules Capital, Inc., or Hercules, pursuant to which a term loan in an aggregate principal amount up to $50.0 million, or the Term Loan Facility, is available to us in three tranches. We received $24.6 million, net of $0.4 million of closing charges, upon signing the agreement on October 29, 2019 and, subject to certain conditions, two additional tranches of $12.5 million each will be available to us.

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.

As of September 30, 2019, we had cash, cash equivalents and investments totaling $83.8 million and an accumulated deficit of $440.9 million. Based on our current plans and forecasted expenses, we believe that our cash, cash equivalents and investments as of September 30, 2019, and the $25.0 million we have drawn from the Term Loan Facility, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2021, 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, and the second and third of which become due in January 2020 and January 2021, respectively. 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.

Loan and Security Agreement with Hercules

In October 2019, we entered into a loan and security agreement with Hercules, pursuant to which the Term Loan Facility is available to us in three tranches. We received the first tranche of $25.0 million upon signing the agreement on October 29, 2019. Upon satisfaction of certain milestones, the second tranche will be available and will allow us to borrow an additional amount up to $12.5 million through March 15, 2021. 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 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.

Cash Flows

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

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
	(in thousands)	
Cash (used in) operating activities	$ (62,473)	$ (75,520)
Cash provided by (used in) investing activities	(35,171)	94,922
Cash provided by (used in) financing activities	61,121	223
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (36,523)	$ 19,625

Operating Activities

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 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.

During the nine months ended September 30, 2018, operating activities used $75.5 million of cash, primarily due to a net loss of $77.7 million and cash used from changes in our operating assets and liabilities of $16.4 million, partially offset by non-cash charges of $18.6 million. Net cash used for changes in our operating assets and liabilities during the nine months ended September 30, 2018 consisted of an increase in accrued expenses and other current liabilities of $1.3 million, an increase in accounts payable of $0.1 million, and an increase in prepaid expenses and other current assets of $1.5 million. The increases were partially offset by a decrease in deferred revenue of $16.3 million. The increase in accrued expenses and increase in accounts payable were due to the timing of payments. The decrease in deferred revenue was primarily due to recognition of $16.7 million in collaboration revenue during the nine months ended September 30, 2018.

Investing Activities

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.

During the nine months ended September 30, 2018, net cash provided by investing activities was $94.9 million, consisting of sales and maturities of investments of $118.9 million. The increase was partially offset by purchases of investments of $21.8 million and purchases of property and equipment of $2.1 million.

Financing Activities

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.

During the nine months ended September 30, 2018, net cash provided by financing activities was $0.2 million in connection with the issuance of common stock under our ESPP and $0.2 million from the issuance of common stock and exercise of stock options. These were partially offset by payments for employee tax obligations relating to vesting of restricted stock units of $0.2 million.

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:

- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC;
- continue the clinical development of SER-109 in our Phase 3 clinical study for the prevention of recurrent CDI;
- 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 continue preclinical development of SER-301 for the treatment of UC;
- make strategic investments in manufacturing 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 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. 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.

Contractual Obligations and Commitments

The disclosure of our contractual obligations and commitments was included in our Annual Report. Since the filing of our Annual Report we have entered into a sublease agreement, refer to Note 9 Leases for further information on this agreement and the loan and security agreement with Hercules. There have been no other material changes from the contractual commitments and obligations previously disclosed in our Annual Report.

Off-Balance Sheet Arrangements

As of September 30, 2019, 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, 2019, 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.

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 (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, 2019.

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, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

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.

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this Quarterly Report on Form 10-Q. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline.

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 $98.9 million for the year ended December 31, 2018, and $51.5 million for the nine months ended September 30, 2019. As of September 30, 2019, we had an accumulated deficit of $440.9 million. To date, we have financed our operations through the public offerings of our common stock, private placements of our preferred stock, payments under our collaboration agreements, and loan financing. 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 therapeutics, 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:

- continue the clinical development of SER-287 in our Phase 2b clinical trial for the treatment of UC and potential other studies of IBD;
- continue the clinical development of SER-109 in our Phase 3 clinical study for the prevention of recurrent CDI;
- 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 continue preclinical development of additional Ecobiotic microbiome therapeutic candidates, including SER-301 for the treatment of UC;
- make strategic investments in manufacturing capabilities;
- maintain and augment our intellectual property portfolio and opportunistically acquire complementary intellectual property;
- scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- perform our obligations under the collaboration agreement with NHS;
- 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-287, including conducting the Phase 2b clinical study, continue the clinical development of SER-109, including conducting the Phase 3 clinical study, continue clinical studies of SER-401, and continue to research, develop and initiate clinical trials of SER-301 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, 2019 and the $25.0 million we have drawn from the Term Loan Facility will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2021, 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 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, including SER-301;
- 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. 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 completed our Phase 1b and a Phase 2 clinical study of SER-109 and have reported top-line data in our Phase 1b studies of SER-287 and SER-262. We have not yet demonstrated our ability to successfully complete any Phase 3 clinical study or other pivotal clinical trials, 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 therapeutics. 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 therapeutic approach that is designed to prevent infection and treat disease by restoring the function of a dysbiotic microbiome. 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 therapeutics 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. 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. Preliminary or topline data remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or interim data we previously published. As a result, these data should be viewed with caution until the final data are available. Adverse changes between preliminary or interim data and final data could significantly harm our business prospects.

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. For example, based on feedback from the FDA, the smaller study design of our Phase 3 clinical trial for SER-109 could require additional confirmatory evidence of efficacy, such as a second Phase 3 clinical trial.

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.

In June 2017, we initiated a Phase 3 clinical study of SER-109 (ECOSPOR III) in patients with multiple recurrent CDI. In May 2019 we implemented modifications to the Phase 3 study design, reducing the size of the study to 188 patients. 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.

Our product development costs will increase if we 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.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be 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. We are developing SER-109, to reduce recurrence of CDI in patients suffering from recurrent CDI. 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 continue to enroll the SER-109 Phase 3 study for patients with recurrent CDI despite the widespread use of unapproved, FMT to treat CDI. As interference from this uncontrolled procedure has impacted the enrollment rate of our placebo-controlled clinical trial, we modified the study design with the goal of expediting clinical results. Enrollment delays in our clinical trials would result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

The reduction in trial size of our ongoing Phase 3 trial of SER- 109 may make it make it necessary to conduct an additional clinical trial of SER-109 to generate sufficient safety and efficacy data to allow us to gain approval of SER-109.

The FDA has previously indicated that an ECOSPOR III trial could be sufficient to allow us to file a BLA for SER-109 if the trial demonstrated a sufficient level of statistical significance. The decrease of the statistical power of the trial resulting from the reduction in the size of the trial from 320 patients to 188 patients may reduce the likelihood that the trial demonstrates the heightened level of statistical significance required by the FDA. The FDA has also indicated that the smaller study could require additional confirmatory evidence of efficacy for approval, which may include conducting a second Phase 3 study prior to seeking approval of SER-109. Moreover, as a result of the smaller study 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.

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 therapeutics. 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. 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 affecting our Ecobiotic microbiome therapeutics that could adversely affect our product 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.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. 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. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA 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.

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 21st 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 and civil monetary penalties laws, including the federal False Claims Act, which, 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, certain other healthcare professionals 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.

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.

There have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future, particularly in light of the current Presidential administration and Congress. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA as well as recent efforts by the current Presidential administration to repeal or replace certain aspects of the ACA. For example, President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, 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 inseverable 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. While the current Presidential administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal, it is unclear how this decision, subsequent appeals and other efforts to repeal and 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 2027 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 18 active patent application families. Of these, 10 applications have been nationalized and 3 are pending at the provisional stage. While we have obtained 12 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*." 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. We expect The University of Tokyo to appeal.

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.

Risks Related to Our Operations

Our new corporate strategy and restructuring may not be successful.

On February 7, 2019, following a strategic business review, we announced our new strategy to focus our resources on advancing our highest-priority, clinical-stage microbiome therapeutic candidates. As a result, we are concentrating on completing the SER-287 Phase 2b study in mild-to-moderate UC patients, obtaining results from the ongoing SER-109 Phase 3 study for recurrent CDI, advancing the SER-401 Phase 1b study, in collaboration with PICI and MD Anderson, to evaluate augmenting checkpoint inhibitor response in patients with metastatic melanoma and advancing SER-301 into clinical development. The success of this strategic shift will depend on our ability to successfully advance our therapeutic candidates, complete our ongoing studies, retain senior management or other highly qualified personnel, prioritize competing projects and efforts and obtain sufficient resources, including additional capital. Accordingly, there are no assurances our change in strategic focus will be successful, which may have an adverse effect on our results of operations and financial condition.

Also, on February 7, 2019, we announced the restructuring of our executive team and a reduction in our workforce by approximately 30 percent. The positions eliminated were primarily related to research, manufacturing, and general and administrative services. Following the reduction in workforce, we have approximately 100 full-time employees, and we believe we are appropriately resourced to continue executing on our current strategy. However, our workforce may not be sufficient to fully execute our strategic shift, and we may not be able to effectively retain the management or personnel needed to fully implement our strategy. Our restructuring and reduction in workforce activities may also result in unexpected risks or costs, such as employee claims and contractual disputes, and the risk that the actual financial and other impacts of the reductions could vary materially from the outcomes anticipated, which may have a material adverse effect on our results of operations or financial condition.

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. 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 plan to rely on collaborators, including NHS, to commercialize any approved products outside of the United States. 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 security measures, 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, 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, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. 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 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.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government recently enacted comprehensive federal income tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our common stock.

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, 2018, we had net operating loss carryforwards, or NOLs, of $185.6 million for federal income tax purposes and $185.9 million for state income tax purposes, which may be available to offset our future taxable income, if any. Our NOLs begin to expire in various amounts in 2035, provided that NOLs generated after December 31, 2017 will not be subject to expiration. As of December 31, 2018, we also had federal and state research and development and other tax credit carryforwards of approximately $28.6 million and $4.9 million, respectively, available to reduce future tax liabilities. Our tax credit carryforwards begin to expire in various amounts in 2035. The federal research and development tax credits include an orphan drug credit carryforward of $17.5 million, which does not expire. These NOLs and tax credit carryforwards could expire unused, to the extent subject to expiration, and be unavailable to offset future 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. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing 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. The reduction of the corporate tax rate under the Tax Cuts and Jobs Act of 2017, or TCJA, from 35% to 21% may cause a reduction in the economic benefit of our NOLs and other deferred tax assets available to us. Furthermore, under the TCJA, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond will 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.

On October 29, 2019, we entered into a loan and security agreement with Hercules for the Term Loan Facility. Under the Term Loan Facility, funds are available to us in three tranches. We received the first tranche of $25.0 million on October 29, 2019. Upon satisfaction of certain milestones, the second tranche will be available and will allow us to borrow an additional amount up to $12.5 million through March 15, 2021. 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 62% 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. Moreover, holders of an aggregate of approximately 18.3 million shares of our common stock, as of September 30, 2019 have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 promulgated under the Securities Act of 1933, as amended, or the Securities Act, or until the rights terminate pursuant to the terms of the investors' rights agreement between us and such holders. 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 the last day of the fiscal year following the fifth anniversary of the closing of the initial public offering of our common stock. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. 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	Incorporated by Reference: Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation, filed on July 1, 2015	8-K	001-37465	3.1	7/1/15	
3.2	Amended and Restated Bylaws	8-K	001-37465	3.2	7/1/15	
4.1	Amended and Restated Investors' Rights Agreement, dated December 19, 2014, by and between the Registrant and each of the investors listed on Schedule A thereto	S-1	333-204484	4.1	5/27/15	
10.1#	Employment Agreement, dated July 11, 2019, by and between the Registrant and Marcus Chapman					*
10.2#	Loan and Security Agreement, dated October 29, 2019, between the Registrant and Hercules Capital, Inc.	8-K	001-37465	10.1	11/4/19	
10.3	Sublease Agreement dated July 1, 2019, by and between the Registrant and Flagship VL56, Inc. and Flagship VL58, Inc.					*
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a)/15d-14(a) Certification of Principal Financial and Accounting Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Principal Financial and Accounting Officer					**
101.INS	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*

* 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 5, 2019

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

EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement"), dated as of July 11, 2019 (the "Effective Date"), is made by and between Seres Therapeutics, Inc., a Delaware corporation (together with any successor thereto, the "Company"), and Marcus Chapman ("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 continue to be employed by the Company on the terms herein provided.

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, 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 Vice President, Principal Financial and Accounting 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 $310,000 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 30% 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. 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.

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 (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 21st 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:

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(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 21st day following Executive's Separation from Service, and not revoking, the Release, 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.

Executive will continue to be bound by the Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment Agreement by and between the Company and Executive dated April 2, 2015 (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, including without limitation the employment offer letter agreement between Executive and the Company dated February 24, 2015. 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, 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; provided, that Executive submits Executive's reimbursement request promptly following the date the expense is incurred, 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 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. <u>Executive Acknowledgement</u>.

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 D. Shaff
Title: President and Chief Executive Officer

/s/ Marcus Chapman
Marcus Chapman

[Signature Page to Employment Agreement]

<u>EXHIBIT A</u>

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between Marcus Chapman ("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 _______________2019 (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. <u>Severance Payments; Salary and Benefits</u>. 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 their 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 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 Effective Date of this Agreement (as defined in Section 7 below), 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; and

(h) 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, 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 such monetary relief from the Company or any Releasee), 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 Effective Date of 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; (c) Executive has 7 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. 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.

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

6. 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.

7. Effective Date. If Executive has attained or is over the age of 40 as of the date of Executive's termination of employment, then each Party has seven days after that Party signs this Agreement to revoke it and this Agreement will become effective on the eighth day after Executive signed this Agreement, so long as it has been signed by the Parties and has not been revoked by either Party before that date (the "Effective Date"). If Executive has not attained the age of 40 as of the date of Executive's termination of employment, then the "Effective Date" shall be the date on which Executive signs this Agreement.

8. 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: ______________________________ ______________________________
Marcus Chapman

SERES THERAPEUTICS, INC.

Dated: ______________________________ By: ______________________________
Name:
Title:

SUBLEASE AGREEMENT

This Sublease Agreement (this **"Sublease")**, made as of the 1 day of July, 2019 (the **"Effective Date")**, by and between SERES THERAPEUTICS, INC., a Delaware corporation, having an office at 200 Sidney Street, Cambridge, Massachusetts (hereinafter referred to as **"Sublandlord")**, and FLAGSHIP VL56, INC., a Delaware corporation **("VL56")**, and FLAGSHIP VL58, INC., a Delaware corporation **("VL58")**, each having an office at 55 Cambridge Parkway, Suite 800E, Cambridge, Massachusetts 02142 (hereinafter referred to jointly and severally, as **"Subtenant")**;

W I T N E S S E T H:

WHEREAS, by a Lease dated as of November 11, 2015 (the **"Master Lease")**, BMR- SIDNEY RESEARCH CAMPUS, LLC (f/k/a BMR-200 Sidney Street LLC), a Delaware limited liability company (hereinafter referred to as **"Master Landlord")** leased to Sublandlord, as tenant, certain premises containing approximately 83,396 rentable square feet located on the first (1st) floor, second (2nd) floor, fourth (4th) floor, and in the basement (the **"Premises")**, in the building known as 200 Sidney Street, Cambridge, Massachusetts (the **"Building")**, upon and subject to the terms and conditions set forth in the Master Lease; and

WHEREAS, Sublandlord desires to sublease to Subtenant and Subtenant desires to sublease from Sublandlord that portion of the Premises on the second (2nd) floor comprising 15,768 rentable square feet approximately **("Leaseable Square Footage of Subleased Premises")** comprised of (i) approximately 14,218 rentable square feet (the **"Initial Subleased Premises")** and (ii) approximately 1,550 rentable square feet (the **"Additional Subleased Premises")** as more particularly shown on **Exhibit A** attached hereto (the Initial Subleased Premises and the Additional Subleased Premises, the **"Subleased Premises")**, on the terms and conditions set forth in this Sublease. A true and correct copy of the Master Lease is attached hereto as **Exhibit B**.

NOW, THEREFORE, the parties hereto, for themselves, their successors and assigns, mutually covenant and agree as follows:

1. Capitalized Terms. Any capitalized terms not otherwise defined in this Sublease shall have the meanings ascribed thereto in the Master Lease.

2. Subleasing. Sublandlord hereby subleases to Subtenant and Subtenant hereby subleases from Sublandlord the Subleased Premises, together with the right to exercise, in common with Sublandlord and others entitled thereto, Sublandlord's right to use the common areas under the Master Lease necessary or appropriate to Subtenant's use of the Subleased Premises.

3. Delivery of the Subleased Premises. Sublandlord shall deliver the Subleased Premises to Subtenant in its as-is, where-is condition; provided, however, Sublandlord shall be obligated to deliver the space (i) in broom clean condition, (ii) free and clear of all tenants and occupants, and (iii) free of all of Sublandlord's personal property, except as expressly set forth herein. Sublandlord has made no representations, warranties or undertakings as to the present or future condition of the Subleased Premises or the fitness and availability of the Subleased Premises for any particular use. Subtenant shall perform all work to make the Subleased Premises complete for Subtenant's use, subject to the provisions of the Master Lease, as incorporated in this Sublease by reference.

4. Term. The term of this Sublease **("Term")** with respect to the Initial Subleased Premises shall commence on the date vacant possession of the Subleased Premises is delivered by Sublandlord (the **"Term Commencement Date")** and shall end on the last day of the twenty-fourth (24th) full calendar month immediately following the Term Commencement Date, or on such earlier date upon which said Term may expire or be terminated pursuant to any of the conditions or limitations or other provisions of this Sublease or pursuant to law (which date for the termination of the term hereof shall hereafter be called the **"Termination Date")**. The Term with respect to the Additional Subleased Premises shall commence on the date the Sublandlord delivers the Additional Subleased Premises to Subtenant (the **"Additional Subleased Premises Commencement Date")**. Promptly following the final determination of the Initial Subleased Premises Commencement Date and the Additional Subleased Premises Commencement Date and upon request of Sublandlord, Sublandlord and Subtenant shall jointly execute a written declaration specifying the actual Initial Subleased Premises Commencement Date and the Additional Subleased Premises Commencement Date. Subtenant shall surrender the Subleased Premises upon the Termination Date in the condition required under the Master Lease; provided, however, in no event shall Subtenant be obligated to restore any alterations or improvements currently existing in the Subleased Premises as of the Term Commencement Date unless otherwise expressly set forth herein.

5. Rent.

(a) Fixed Annual Rent. From and after the Term Commencement Date, the Subtenant shall pay to Sublandlord, as fixed annual rent **("Fixed Annual Rent"),** the amounts set forth below, in advance on the first (1st) day of each calendar month during the Term of this Sublease, without set-off, abatement, deduction or demand, except as expressly set forth herein. Fixed Annual Rent due for any partial month at the beginning or end of the term shall be prorated on a per diem basis.

DATES	**FIXED ANNUAL RENT PER SQUARE FOOT OF RENTABLE AREA**	**FIXED ANNUAL RENTAL RATE**	**MONTHLY INSTALLMENTS OF FIXED ANNUAL RENT**
Sublease Year 1, from the Term Commencement Date through the day immediately prior to the Additional Subleased Premises Commencement Date	$78.00	$1,109,004.00	$92,417.00
Sublease Year 1, from the Additional Subleased Premises Commencement Date through the end of Sublease Year 1	$78.00	$1,229,904.00	$102,492.00
Sublease Year 2	$80.34	$1,266,801.12	$105,566.76

For purposes of this Sublease, **"Sublease Year"** shall mean each successive twelve (12) month period during the Term, with the first such Sublease Year commencing on the Term Commencement Date and each successive Sublease Year commencing on the next succeeding anniversary of the Term Commencement Date; provided, however, (i) the final Sublease Year shall expire on the Termination Date, and (ii) if the Term Commencement Date does not occur on the first day of a calendar month, then the first Sublease Year shall include the partial calendar month in which the first anniversary of the Term Commencement Date occurs, and the remaining Sublease Years shall be the successive twelve (12) month periods following the end of the first Sublease Year.

The rights and obligations to pay Rent under this Section 5(a) shall survive the expiration or earlier termination of this Sublease; and for the avoidance of doubt, in the event such deferral results in Rent being outstanding following the expiration or earlier termination of this Sublease, such payment shall remain an outstanding obligation of Subtenant regardless of the expiration or earlier termination of this Sublease.

(b) Additional Rent.

i. All amounts other than Fixed Annual Rent that are due to Sublandlord from Subtenant under this Sublease are hereinafter referred to collectively as **"Additional Rent,"** and Fixed Annual Rent and Additional Rent may be referred to collectively as **"Rent."**

ii. During the Term, Subtenant shall pay to Sublandlord, as Additional Rent in the manner and at the same time as set forth in Section 5(a) above with respect to Fixed Annual Rent, Subtenant's Share (as hereinafter defined) of (i) Tenant's Adjusted Share of Operating Expenses, and (ii) the Property Management Fee, all based upon the amounts of, as applicable, billed to Sublandlord pursuant to Article 9 of the Master Lease and (iii) all amounts required to be paid pursuant to Section 16 of the Master Lease that are attributable to the Subleased Premises including, without limitation, costs for all water (including the cost to service, repair and replace reverse osmosis, de-ionized and other treated water), gas, heat, light, power, telephone, internet service, cable television, other telecommunications and other utilities supplied to the Premises, together with any fees, surcharges and taxes thereon, electricity, HVAC airflow and gas). As used herein, the term **"Subtenant's Share"** shall mean 18.91% of Tenant's Adjusted Share. Sublandlord shall, within a reasonable period of time after Sublandlord receives corresponding notices or statements from Master Landlord of the estimated monthly payments of Additional Rent due under Article 9 of the Master Lease for the Premises, provide to Subtenant a good faith estimate of the Additional Rent payable from Subtenant under this Section 5(b) for any calendar year (or part thereof) during the Term of this Sublease that such amounts are due and Subtenant shall pay to Sublandlord, at the times and in the manner set forth in Section 5(a) above with respect to Fixed Annual Rent, an amount equal to 1/12th of such estimated Additional Rent due for such calendar year or part thereof. Within thirty (30) days following receipt by Sublandlord of Master Landlord's annual reconciliation statement of Operating Expenses, Sublandlord will send to Subtenant a statement together with relevant, non-confidential documentation, establishing the actual payment, as applicable, for such year. If Subtenant has paid more in estimated Additional Rent under this Section than the actual amount due from Subtenant for the applicable year, Sublandlord shall credit such excess against subsequent obligations of Subtenant for Additional Rent (or refund such excess to Subtenant within thirty (30) days if the Term of this Sublease has ended and Subtenant has no further obligation to Sublandlord). If Subtenant has paid less than the actual Additional Rent due under this Section 5(b), Subtenant shall pay any deficiency to Sublandlord within twenty (20) days following receipt of the reconciliation documentation from Sublandlord.

(c) <u>Intentionally omitted</u>.

(d) Additional Charges. Subtenant shall also be responsible for its own utilities, including telephone, facsimile transmitter, internet access, photocopier, and its other business expenses. In addition, if Subtenant shall procure any additional services from Master Landlord, including without limitation after-hours HVAC, or if additional rent or other sums are incurred for Subtenant's sole benefit, including, without limitation, extra janitorial services, repairs and replacements to the Subleased Premises caused or permitted by Subtenant, Subtenant shall make such payment to Sublandlord within twenty (20) days after Subtenant's receipt of an invoice. Any rent or other sums payable by Subtenant to Sublandlord under this Section 5(d) shall constitute and be due as **"Rent."**

(e) Abatement of Rent Under the Master Lease. Notwithstanding anything in this Sublease to the contrary, if the rent due under the Master Lease with respect to the Subleased Premises is abated in whole or in part during the Term pursuant to the terms of Sections 16.2 or 24.5 of the Master Lease, or any other applicable provision of the Master Lease, then the Fixed Annual Rent and Additional Rent due under this Sublease shall abate for the same period and to the same extent as the rent for the Premises is abated pursuant to such section of the Master Lease, or any other provision of the Master Lease, as applicable.

6. Insurance. Subtenant shall obtain and maintain all insurance types and coverage as specified in the Master Lease to be obtained and maintained by Sublandlord, as tenant, in amounts not less than those specified in the Master Lease. All such policies of insurance shall name Master Landlord and Sublandlord as additional insureds thereunder. Subtenant's insurance shall be primary over Master Landlord's and Sublandlord's insurance.

7. Indemnification. Notwithstanding any other provision of this Sublease or the Master Lease to the contrary, but subject to the waiver of subrogation provided in Section 23.6 of the Master Lease, Subtenant will save Master Landlord and Sublandlord harmless, and will exonerate and indemnify Master Landlord and Sublandlord, from and against any and all claims, liabilities or penalties asserted by or on behalf of any person, firm, corporation or public authority:

(a) On account of or based upon any injury to person, or loss of or damage to property sustained or occurring on the Subleased Premises on account of or based upon the act, omission, fault, negligence or misconduct of any person whomsoever (other than Master Landlord and Sublandlord or their respective agents, contractors or employees);

(b) On account of or based upon any injury to person or loss of or damage to property, sustained or occurring elsewhere (other than on the Subleased Premises) in or about the Building (and, in particular, without limiting the generality of the foregoing on or about the elevators, stairways, public corridors, sidewalks, concourses, arcades, malls, galleries, vehicular tunnels, approaches, areaways, roof, or other appurtenances and facilities used in connection with the Building or the Subleased Premises) arising out of the negligent act or omission or willful misconduct of Subtenant, its agents, employees or invitees;

(c) On account of or based upon (including monies due on account of) any work or thing whatsoever done (other than by Master Landlord or Sublandlord or their respective contractors, agents or employees of either) on the Subleased Premises during the term of this Sublease and during the period of time, if any, prior to the Term Commencement Date that Subtenant may have been given access to the Subleased Premises; and

(d) On account of or resulting from the failure of Subtenant to perform and discharge any of its covenants and obligations under this Sublease.

If either of the Master Landlord or the Sublandlord shall, without fault on its part, be made a party of any litigation commenced by or against the Subtenant, then the Subtenant shall protect, indemnify and hold the Master Landlord or the Sublandlord harmless and shall pay all costs, expenses and reasonable legal fees incurred or paid by the Master Landlord or the Sublandlord in connection with such litigation. The Subtenant shall also pay all costs, expenses and reasonable legal fees (on a solicitor and his client basis) that may be incurred or paid by the Master Landlord or the Sublandlord in enforcing the terms, covenants and conditions in this Sublease unless a court shall decide otherwise.

Subtenant shall neither do nor permit anything to be done which would cause a default under the Master Lease, or termination or forfeiture by reason of any right of termination or forfeiture, reserved or vested in the Master Landlord under the Master Lease, and Subtenant shall indemnify and hold Sublandlord harmless from and against all claims of any kind whatsoever by reason of breach or default on the part of Subtenant, or termination or forfeiture which is the consequence of any such breach or default.

8. Sublandlord Covenants and Representations.

(a) Sublandlord covenants and agrees that Sublandlord: (i) shall cause all rent to be paid under the Master Lease as and when due and payable under the Master Lease; (ii) shall observe and perform the other terms, provisions, covenants and conditions of the Master Lease to be observed and performed by Sublandlord, except and to the extent that such terms, provisions, covenants and conditions are assumed by Subtenant hereunder; (iii) shall not voluntarily terminate the Master Lease except pursuant to a right of termination arising out of casualty or condemnation expressly set forth in the Master Lease and shall not amend the Master Lease in a manner adverse to Subtenant in any material respect; (iv) shall not take any action or fail to perform any act that results in a breach or default under the Master Lease to the extent any such failure to perform such act adversely affects the rights of Subtenant under this Sublease, including, without limitation, the right of Subtenant to receive all services, utilities, repairs and restorations to be provided by Master Landlord to Sublandlord under the Master Lease with respect to the Subleased Premises or the ability of Subtenant to seek or obtain the approval or consent of Master Landlord or the right of Subtenant to use and occupy the Subleased Premises for the purposes set forth in this Sublease. Sublandlord shall not be deemed to have made any representation made by Master Landlord in any of the incorporated provisions. Should the Master Lease expire or terminate during the Term for any reason, this Sublease shall terminate on the date of such expiration or termination of the Master Lease, with the same force and effect as if such expiration or termination date had been specified in this Sublease as the Termination Date and Sublandlord shall have no liability to Subtenant in the event of any such expiration or termination.

(b) Sublandlord represents and warrants to Subtenant that:

i. Sublandlord has not received any written notice of default under the Master Lease, except for any defaults that Sublandlord has cured and Master Landlord is no longer claiming to exist, and to the actual knowledge, without any investigation, of Sublandlord, Sublandlord is not in default of any of Sublandlord’s obligations under the Master Lease;

ii. Sublandlord has not sent to Master Landlord any written notice stating that Master Landlord is in default of any of Master Landlord’s obligations under the Master Lease, and to the actual knowledge, without any investigation, of Sublandlord, Master Landlord is not in default of any of Master Landlord’s obligations under the Master Lease;

iii. Sublandlord has not received any written notice that any work is required under the Master Lease or by applicable law to be done in the Subleased Premises; and

iv. Sublandlord has not received any written notice of violation of any laws, ordinances, codes, rules, regulations or requirements affecting the Subleased Premises.

9. Incorporation of the Master Lease by Reference.

(a) Except to the extent such terms and provisions are inconsistent with or are specifically contrary to the express written provisions of this Sublease and except as provided in this Section 9, all of the terms, covenants and conditions of the Master Lease are by this reference incorporated herein and made a part of this Sublease with the same force and effect as if fully set forth herein, provided, however, that for purposes of such incorporation, (i) the term “Lease” as used in the Master Lease shall refer to this Sublease; (ii) the term “Landlord” (and other defined terms containing the term “Landlord” or any derivative thereof) as used in the Master Lease, and subject to the limitations of Sublandlord’s responsibilities to Subtenant under the Master Lease set forth in Section 10 of this Sublease, shall refer to Sublandlord; (iii) the term “Tenant” (and other defined terms containing the term “Tenant” or any derivative thereof) as used in the Master Lease shall refer to Subtenant; (iv) the term “Term” as used in the Master Lease shall refer to the Term defined herein; (v) the term “Term Expiration Date” as used in the Master Lease shall mean the Termination Date of this Sublease; (vi) the term “Premises,” as used in the Master Lease shall refer to the Subleased Premises; and (vii) the term “Base Rent” as used in the Master Lease shall refer to the Fixed Annual Rent due under this Sublease. In the event of any inconsistency between the provisions set forth in this Sublease and the provisions of the Master Lease, as incorporated herein, the provisions of this Sublease shall control as between Sublandlord and Subtenant. Notwithstanding the foregoing, the following provisions of the Master Lease are expressly not incorporated into this Sublease: (1) the definitions of Rent Commencement Date, Security Deposit, Landlord’s Work, Tenant Improvements, Additional Amount, Base TI Allowance, TI Allowance, and any and all definitions or terms which are defined in or included in any of the Excluded Master Lease Provisions (as hereinafter defined) set forth in the Master Lease (except to the extent used or referred to in this Sublease), (2) all within the Master Lease: Articles 4, 11, 33, 41, 42 and 43; and (3) such other terms of the Master Lease which are inapplicable, inconsistent with, or specifically modified by the terms of this Sublease (collectively, the **“Excluded Master Lease Provisions”)**. Any reference to an allowance in the Master Lease is not incorporated herein.

(b) Sublandlord shall have all of the same rights and remedies with respect to the Subleased Premises as Master Landlord has with respect thereto under the Master Lease. This Sublease is expressly subject and subordinate to any mortgages or deeds of trust and all matters of record, ground leases and underlying leases to which the Master Lease is now or hereafter subject and subordinate pursuant to the Master Lease without the requirement of delivering any subordination, attornment and non-disturbance agreement or other agreements to Subtenant.

(c) With respect to any of Subtenant’s obligations to be performed under this Sublease, when the Master Lease grants Sublandlord a specific number of days to perform its obligations thereunder, Subtenant shall perform such obligation not later than the date that is three (3) business days prior to the date Sublandlord is obligated under the Master Lease to perform such obligation; provided, however, in no event shall Subtenant have less than five (5) days with which to perform any monetary obligations prior to a default being claimed in accordance with Section 15 hereof. Wherever in the Master Lease there is a specific number of days for Master Landlord to respond to a request from Tenant for consent or approval, Sublandlord shall have an additional five (5) business days to respond to any such request (including a second notice) from Subtenant under this Sublease. In the event of any conflict between the provisions of the Master Lease and this Sublease, the Master Lease shall govern and control except to the extent directly contradicted by the provisions of this Sublease.

10. Benefits of the Master Lease. Sublandlord agrees that Subtenant shall be entitled to receive all services, utilities, repairs and restorations to be provided by Master Landlord to Sublandlord under the Master Lease with respect to the Subleased Premises. Subtenant shall look solely to Master Landlord for all such services, utilities, repairs and restorations and shall not require Sublandlord to perform any such services, utilities, repairs and restorations. Sublandlord shall not be obligated (i) to provide any of the services or utilities, including cleaning, that Master Landlord has agreed to provide in the Master Lease, (ii) make any of the repairs or restorations that Master Landlord has agreed in the Master Lease to make, (iii) take any action that Master Landlord has agreed in the Master Lease to take and Sublandlord shall have no liability to Subtenant on account of any failure of Master Landlord to do so. Sublandlord agrees, upon Subtenant's request, to use reasonable efforts at Subtenant's expense to (a) cause Master Landlord to provide the services or utilities or make the repairs or restorations described in the Master Lease, or (b) to obtain Master Landlord's consent or approval wherever required by the Master Lease. Sublandlord agrees that if under the Master Lease any right or remedy of Sublandlord or any duty or obligation of Master Landlord is subject to or conditioned upon Sublandlord making any demand upon Master Landlord or giving any notice or request to Master Landlord then, if Subtenant shall so request, Sublandlord, at Subtenant's expense, shall make such demand or give such notice or request on Sublandlord's behalf, except that Sublandlord shall not be required to do so with respect to any act or thing as to which Sublandlord shall have determined in accordance with this Sublease to withhold its consent or approval.

11. Direct Performance. At any time by written notice to Subtenant, Sublandlord may elect to require Subtenant to perform its obligations under this Sublease directly to Master Landlord, and Subtenant shall do so on Sublandlord's election, in which event Subtenant shall send to Sublandlord from time to time copies of all notices and other communications that it shall send to and receive from Master Landlord. Subtenant may also perform Sublandlord's obligations if directed in writing by Master Landlord and thereafter shall be released of the obligation to perform such obligations to Sublandlord until directed in writing by Master Landlord.

12. Repairs; Alterations.

(a) Approval Required. Subtenant at its own cost shall keep the Subleased Premises in good condition and repair and in accordance with the applicable terms of the Master Lease. Subtenant shall not perform or cause to be performed any interior or exterior improvements to the Subleased Premises **("Subtenant Alterations")** without the prior written consent of Master Landlord (in accordance with the terms of the Master Lease) and Sub landlord, to be granted or withheld in Sublandlord's reasonable discretion. Subtenant shall reimburse Master Landlord, if applicable, in accordance with the terms and conditions of the Master Lease, and Sublandlord for all reasonable third party out of pocket costs Sublandlord may incur in connection with reviewing Subtenant's proposed Subtenant Alterations.

(b) Removal. Prior to expiration of the Term or earlier termination of this Sublease, if Sublandlord so directs, Subtenant shall remove all of the Subtenant Alterations and restore the Subleased Premises to the same condition as of the Term Commencement Date, ordinary wear and tear excepted (this exception will not apply to any condition resulting from misuse or improper care or maintenance of the Subleased Premises by Subtenant or its agents, employees, contractors or invitees). Subtenant may request in writing to Sublandlord at the time Subtenant presents any plans to Sublandlord for review that Sublandlord designate whether Sublandlord will require that the proposed alterations shown on the plans be removed at the expiration or earlier termination of the Term of this Sublease and, if such so requested in writing, Sublandlord agrees, if expressly requested by Subtenant in writing, to make such designation at the time Sublandlord reviews and responds to Subtenant's plans, provided, however, Sublandlord may defer notification until Master Landlord responds to such request in accordance with the terms of the Master Lease.

13. Assigning and Subletting.

(a) Consent May Be Required. Subject to the terms and conditions of the Master Lease, during the first twelve (12) month period of the Term, Subtenant shall be entitled to sub-sublease or sub-license all or a portion of the Subleased Premises to a portfolio company of Flagship Pioneering, Inc. During such period, the total number of sub-subleases or sub-licenses (not including the Sublease) shall not exceed two (2). For the avoidance of doubt, each of VL56 and VL58 would be entitled to sub-sublease or sub-license to an additional Flagship Pioneering, Inc. company or both could sub-sublease or sub-license to one Flagship Pioneering, Inc. company. Sublandlord's consent shall not be unreasonably withheld, conditioned or delayed to such further sub-subleasing or sub-licensing during the first twelve (12) month period of the Term, and may be withheld in Sublandlord's sole discretion for the remaining twelve (12) month period thereafter.

(b) No Release of Subtenant. Regardless of Sublandlord's and Master Landlord's consent, no subletting or assignment shall release Subtenant of Subtenant's obligation or alter the primary liability of Subtenant to pay the Rent and to perform all other obligations to be performed by Subtenant under this Sublease. The acceptance of Rent by Sublandlord from any other person shall not be deemed to be a waiver by Sublandlord of any provision of this Sublease. In the event of Default by Subtenant or any successor or assignee which remains uncured after any applicable notice and cure periods, if any, Sublandlord may proceed directly against Subtenant without the necessity of exhausting remedies against such assignee, subtenant or successor.

14. Use. Notwithstanding anything to the contrary contained in this Sublease or the Master Lease, Subtenant shall use and occupy the Subleased Premises solely for those uses permitted by the Master Lease and Master Landlord's consent.

15. Default. The occurrence of any of the following shall constitute a material breach of this Sublease and a **"Default"** by Subtenant: (a) failure to pay Rent or any other amount within five (5) days after written notice from Sublandlord to Subtenant of such late payment (a **"monetary default")**; (b) all those items of default set forth in the Master Lease which remain uncured after the cure period provided in the Master Lease, less three (3) business days; and/or (c) Subtenant's failure to perform timely and subject to any cure periods any other material provision of this Sublease or the Master Lease as incorporated herein.

16. Sublandlord Default. For purposes of this Sublease, Sublandlord shall not be deemed in default hereunder unless and until Subtenant shall first deliver to Sublandlord thirty (30) days' prior written notice, and Sublandlord shall fail to cure said default within such thirty (30) day period, or in the event Sublandlord shall reasonably require in excess of thirty (30) days to cure such default, shall fail to commence said cure with such thirty (30) day period, and thereafter diligently to prosecute the same to completion.

17. Security Deposit. Simultaneously with the execution of this Sublease by Subtenant, Subtenant shall deliver to Sublandlord, and that Sublandlord shall hold the same throughout the Term of this Sublease as security for the performance by Subtenant of all obligations on the part of Subtenant hereunder a security deposit in the amount of $204,984.00 (the **"Security Deposit")**. Sublandlord shall have the right from time to time, without prejudice to any other remedy Sublandlord may have on account thereof, to apply such Security Deposit, or any part thereof, to Sublandlord damages arising from, or to cure, any Default by Subtenant. If Sublandlord shall so apply any or all of such Security Deposit, Subtenant shall immediately upon demand deposit with Sublandlord the amount so applied to be held as security hereunder. Sublandlord shall return the Security Deposit, or so much thereof as shall not have theretofore been applied in accordance with the terms of this Section, to Subtenant on the expiration or earlier termination of the Term of this Sublease and surrender of possession of the Subleased Premises by Tenant to Landlord at such time, provided that there is then existing no Default of Subtenant (nor any circumstance which, with the passage of time or the giving of notice, or both, would constitute a Default of Subtenant). While Sublandlord holds such Security Deposit, Sublandlord shall have no obligation to pay interest on the same and shall have the right to commingle the same with Sublandlord's other funds.

Notwithstanding the foregoing, the parties agree that in lieu of delivering the Security Deposit in the form of cash as set forth above, on or before the date that is thirty (30) days following the Effective Date, Subtenant may deliver to Sublandlord a letter of credit from a United States based bank, reasonably acceptable to Sublandlord (it being agreed that Silicon Valley Bank would be acceptable to Sublandlord), in the amount of the Security Deposit (the **"Letter of Credit")**, provided that the Letter of Credit is in a form reasonably satisfactory to Sublandlord. At a minimum such Letter of Credit shall provide for the following: (a) it shall terminate no sooner than the Termination Date, or, if it shall terminate earlier, the Letter of Credit shall provide that it will automatically renew during each year of the Term until the Termination Date, unless Sublandlord (the beneficiary thereof) is notified in writing by the issuer prior to the then expiration date that the Letter of Credit will not be renewed; and if Sublandlord is so notified of such non-renewal, Sublandlord (the beneficiary thereof) shall have the right to draw the full amount of such Letter of Credit prior to such earlier expiration date, and the amounts so drawn shall be held, applied and disbursed in accordance with the terms of this Section 17, (b) it shall be irrevocable, and (c) it shall be transferable to any successor to Sublandlord's interest under the Sublease.

18. Quiet Enjoyment. So long as Subtenant is not in Default (beyond any applicable notice and cure period) under this Sublease, its quiet enjoyment of the Subleased Premises shall not be disturbed or interfered with by Sublandlord or anyone claiming by, through or under Sublandlord.

19. Notice. Any and all communications delivered hereunder shall be in writing and delivered or served in accordance with Section 39 of the Master Lease addressed as follows: if to Master Landlord: as provided in the Master Lease; if to Sublandlord: Seres Therapeutics, Inc., 200 Sidney Street, Cambridge, Massachusetts 02139, ATTN: Chief Financial Officer; and if to Subtenant: VL56, 55 Cambridge Parkway, Suite 800E, Cambridge, Massachusetts 02142, with a copy to Flagship Pioneering, Inc., 55 Cambridge Parkway, Suite 800E, Cambridge, Massachusetts 02142, ATTN: Ken Mace, or to such other address and attention as any of the above shall notify the others in writing.

20. Signage. Subtenant, at Subtenant's sole cost and expense, shall be entitled to building standard signage, provided the same is in accordance with Master Landlord's signage program and subject to Sublandlord's and Master Landlord's prior written consent, which consent of Sublandlord will not be unreasonably withheld. All signage shall comply with the terms of the Master Lease and with all federal, state and local rules, regulations, statutes, and ordinances at all times during the Term.

21. Parking. Pursuant to the terms and conditions of Section 13.4 of the Master Lease, Subtenant shall have the right to use up to sixteen (16) parking spaces on an unreserved basis, in common with Sublandlord, subject to the following terms and conditions:

(a) As of the date of this Sublease, the cost of the parking spaces shall be $290.00 per parking space per month (subject to market rate adjustments by Master Landlord from time to time throughout the Term), which Subtenant shall pay simultaneously with payments of Base Rent.

(b) Subtenant shall at all times abide by and shall cause each of Subtenant's employees, agents, customers, visitors, invitees, licensees, contractors, assignees and subtenants (collectively, "Subtenant's Parties") to abide by any rules and regulations ("Rules") for use of the parking areas to which Sublandlord is subject pursuant to the Master Lease. The parking spaces to which Subtenant has rights hereunder shall be provided on a non-designated "first-come, first-served" basis, subject to the terms of the Master Lease.

(c) Sublessee acknowledges that to the fullest extent permitted by law, Sublandlord shall have no liability for any damage to property or other items located in the parking areas (including without limitation, any loss or damage to Subtenant's automobile or the contents thereof due to theft, vandalism or accident), nor for any personal injuries or death arising out of the use of the parking areas by Subtenant or any Subtenant's Parties. Subtenant agrees to look first to its insurance carrier and to require that Subtenant's Parties look first to their respective property insurance carriers for payment of any property losses sustained in connection with any use of the parking areas. Subtenant hereby waives on behalf of its property insurance carriers all rights of subrogation against Sublandlord or Sublandlord's agents with respect to Subtenant-owned vehicles.

(d) Sublessee's non-exclusive right to park as described in this Section is exclusive to Subtenant and Subtenant's permitted assignees and subtenants and shall not pass to any other assignee or subtenant without the express written consent of Sublandlord. Such consent is at the reasonable discretion of the Sublandlord.

(e) If Subtenant violates any of the terms and conditions of this Section, Sublandlord shall have the right to cancel Subtenant's right to use the parking areas pursuant to this Section upon ten (10) days' written notice specifying in reasonable detail the reasons therefor, unless within such ten (10) day period, Subtenant cures such default. Such cancellation right shall be cumulative and in addition to any other rights or remedies available to Sublandlord at law or equity, or provided under this Sublease.

22. Furniture. Subtenant shall have, as appurtenant to the Subleased Premises, the use of the furniture and art (which rotates from time to time) located in the Subleased Premises as of the Term Commencement Date and more fully shown on the inventory attached hereto as **Exhibit C** (labeled **"Furniture and Art")** during the Term. Subtenant agrees to take all actions necessary or appropriate to ensure that the Furniture shall be and remain personal property, and nothing in this Sublease shall be constituted as conveying to Subtenant any interest in the Furniture other than its interest as a Subtenant. The Furniture shall be used by Subtenant only at the Subleased Premises and in the ordinary conduct of its business. Subtenant shall, at its expense, repair, maintain and replace the Furniture so that it will remain in the same condition as when delivered to Subtenant, ordinary wear and tear from proper use excepted. In addition, Subtenant hereby assumes all other risks and liabilities, including without limitation personal injury or death and property damage, arising with respect to the Furniture (unless through Sublandlord's negligence or willful misconduct), howsoever arising, in connection with any event occurring prior to such Furniture's return in accordance herewith. In addition, as Sublandlord is not the manufacturer or vendor of the Furniture, it makes no other representation or warranty, express or implied, as to any matter whatsoever, including without limitation the design or condition of the Furniture, its merchantability, durability, suitability or fitness for any particular purpose, the quality of the material or workmanship of the Furniture, or the conformity of the Furniture to the provisions or specifications of any purchase order relating thereto, and Sublandlord hereby disclaims any and all such representations and warranties. At the expiration or earlier termination of the Term, Subtenant shall return the Furniture to Sublandlord in the condition required hereunder.

23. Successors and Assigns. This Sublease and everything herein contained shall extend to and bind and inure to the benefit of Sublandlord and its successors and assigns and Subtenant and its heirs, executors, administrators and permitted successors and assigns. No rights shall inure to the benefit of any assignee, subtenant or occupant unless the provisions of Section 29 of the Master Lease and Section 13 of this Sublease are complied with.

24. Miscellaneous.

(a) Time of Essence. Time is of the essence with respect to the performance of every provision of this Sublease in which time of performance is a factor, including, without limitation, the giving of any notice required to be given under this Sublease or by law, the time periods for giving any such notice and for taking of any action with respect to any such notice.

(b) Partial Invalidity. If any term, provision or condition contained in this Sublease shall, to any extent, be invalid or unenforceable, the remainder of this Sublease, or the application of such term, provision or condition to persons or circumstances other than those with respect to which it is invalid or unenforceable, shall not be affected thereby, and each and every other term, provision and condition of this Sublease shall be valid and enforceable to the fullest extent possible permitted by law; provided that, if a material provision is adjudged void or unenforceable, the parties shall negotiate, in good faith, an equitable adjustment to such other provisions of this Sublease as may be necessary or appropriate to effectuate as closely as possible the parties' intent as evidenced by this Sublease.

(c) Entire Agreement. There are no oral agreements between the parties hereto affecting this Sublease and this Sublease constitutes the parties' entire agreement with respect to the leasing of the Subleased Premises and supersedes and cancels any and all previous negotiations, arrangements, letters of intent, agreements and understandings, if any, between the parties, and none thereof shall be used to interpret or construe this Sublease. None of the terms, covenants, conditions or provisions of this Sublease can be modified, deleted or added to except in writing signed by the parties.

(d) Execution. Each individual executing this Sublease on behalf of Sublandlord or Subtenant represents and warrants that he or she has been duly authorized to do so.

(e) Interpretation. Preparation of this Sublease has been a joint effort of the parties and the resulting document shall not be construed more severely against one of the parties than against the other.

(f) Exhibits and Attachments. All Exhibits and attachments to this Sublease are a part hereof.

(g) Counterparts. This Sublease may be executed in counterparts with the same effect as if both parties had executed the same document. Both counterparts shall be construed together and shall constitute a single lease. Pages may be transmitted by facsimile or electronically and each of will be deemed an original. The signature pages of counterpart copies may be assembled to form one instrument.

(h) Limited Liability. In no event shall the partners, principals, members, officers, stockholders, directors, employees or agents of either Sublandlord or Subtenant be personally liable for the performance of that party's obligations under this Sublease. Notwithstanding any indemnities or other provisions hereof to the contrary, in no event shall Sublandlord or Subtenant be responsible for any consequential, incidental, special or punitive damages, except as specifically set forth herein or in the Master Lease.

25. Confidentiality. Each party shall hold the Confidential Information (as hereinafter defined) of the other party in strict confidence and shall not use, or disclose such information to any person, except as explicitly permitted by this Sublease. In protecting the Confidential Information, each party shall use the same degree of care as each party uses to protect its own confidential information of a similar nature (but in no event less than a reasonable degree of care) and shall notify the other party of any potential or actual unauthorized disclosure or use of its Confidential Information.

(a) Each party may disclose the other party's Confidential Information to:

(1) its agents and employees only to the extent reasonably necessary to accomplish the purposes of this Sublease and only with the express agreement by such employees and agents that the Confidential Information is to be maintained under confidentiality and nonuse obligations that are no less protective than those in this Sublease; and

(2) to the extent required by applicable law, court order, or in any litigation in connection with this Sublease.

(b) If either party is required by to disclose any of the other party's Confidential Information pursuant to Section 25(a)(2) above, such party will, if permitted, provide the party whose Confidential Information is being disclosed with reasonable, prior notice of the requirement and assistance (at such party's expense) so that the party that is the owner of the Confidential Information may seek to oppose the requirement to disclose or obtain a protective order preserving the confidentiality of any of its Confidential Information so disclosed.

(c) **"Confidential Information"** shall mean: (a) all business information heard, seen or in any manner learned by either party or its respective agents, employees or Visitors due to the parties' shared use of the Premises; (b) all information that has been or may be disclosed to either party, its employees, or agents orally or in writing, by the other party, its respective employees or agents in connection with, or incidental to, this Sublease or any other business dealing between Sublandlord and Subtenant; and (c) the terms of this Sublease.

The Confidential Information shall not include information that (i) is or becomes available to the public through no fault of a party or its respective agents, employees or Visitors, or (ii) the receiving party can show by written records was acquired in good faith on a non-confidential basis from a third party. **"Visitors"** shall mean: all persons permitted to access the Premises by or because of either party.

(d) Each party shall be directly liable to the other party for breaches of the confidentiality obligations set forth herein by the receiving party and its respective employees, agents and Visitors. Upon a disclosing party's request, the receiving party shall destroy, erase, or return to the disclosing party, in a manner reasonably acceptable to the disclosing party, all Confidential Information in its possession or control.

(e) Each party hereby acknowledges and agrees that money damages alone would be an inadequate remedy for the injuries and damage that would be suffered and incurred by either disclosing party as a result of a breach of any of the confidentiality provisions of this Sublease. Accordingly, a disclosing party shall be entitled to equitable relief, including injunctive relief and specific performance, to prevent or end a breach of the confidentiality provisions of this Sublease without the need to show irreparable harm or to submit proof of the economic value of any Confidential Information. Such equitable relief shall not be deemed to be the exclusive remedy for any breach of this Sublease, but shall be in addition to all other remedies at law or in equity.

(f) Each party's obligations of confidentiality and nonuse of the Confidential Information under this Sublease shall survive the termination of this Sublease.

26. Sublandlord’s Consent. Whenever Sublandlord’s consent is required under this Sublease, Sublandlord’s rejection of a request made by Subtenant shall not deemed unreasonable, in any case, if such rejection is based on Master Landlord’s rejection of such request.

27. Brokers. Sublandlord and Subtenant each hereby represent and warrant that it has not dealt with any broker in connection with this Sublease for the Subleased Premises. Each party shall indemnify the other against any cost or liability resulting from the indemnifying party’s breach of the foregoing representation and warranty. Sublandlord shall be responsible for any commissions owed to the foregoing named brokers, subject to and in accordance with the provisions of separate agreements. This provision shall survive the expiration or sooner termination of this Sublease.

28. Master Landlord’s Consent. This Sublease is expressly conditioned upon Master Landlord’s written consent to this Sublease (the **“Consent to Sublease”),** which Sublandlord shall use commercially reasonable efforts to obtain.

29. Identification of Subtenant. So long as Subtenant constitutes more than one person or entity, (A) each of them shall be jointly and severally liable for the keeping, observing and performing of all of the terms, covenants, conditions and provisions of this Sublease to be kept, observed and performed by Subtenant, (B) the term “Subtenant” as used in this Sublease shall mean and include each of them jointly and severally, and (C) the act of or notice from, or notice or refund to, or the signature of, any one or more of them, with respect to the tenancy of this Sublease, including, but not limited to, any renewal, extension, expiration, termination or modification, of this Sublease, shall be binding upon each and all of the persons or entities executing this Sublease as Subtenant with the same force and effect as if each and all of them had so acted or so given or received such notice or refund or so signed. The initial point of contact that Sublandlord may interact with on behalf of Subtenant shall be VL56, or such other person as designated by Subtenant from time to time.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, Sublandlord and Subtenant have duly executed this Sublease, as an instrument under seal, as of the Effective Date.

SUBLANDLORD:
SERES THERAPEUTICS, INC., a Delaware corporation

By: /s/ Eric Shaff
Name: Eric Shaff
Title: President, CEO

SUBTENANT:
FLAGSHIP VL56, INC. a Delaware corporation

By: /s/ Avak Kahvejian
Name: Avak Kahvejivan
Title: President

FLAGSHIP VL58, INC. a Delaware corporation

By: /s/ Geoffrey von Maltzahn
Name: Geoffrey von Maltzahn
Title: President

EXHIBIT A

PLAN OF SUBLEASED PREMISES

EXHIBIT B

MASTER LEASE

EXHIBIT C

FURNITURE & ART

Area	Amount:	Item:
Reception	1	desk
	1	Under file cab
	1	double file cab
	1	task chair
22-03 (Chuck Yeager)	1	Conf Table
	7	chairs
	1	TV
22-04	1	Desk setup (2 piece)
	1	Round meet table
	2	meet chairs
	1	under file cab
22-05	1	Desk setup (2 piece)
	1	Round meet table
	2	meet chairs
	1	under file cab
22-06	1	Desk setup (2 piece)
	1	Round meet table
	2	meet chairs
	1	under file cab
22-07	1	Desk setup (2 piece)
	1	Round meet table
	2	meet chairs
	2	under file cab
22-08	1	Desk setup (2 piece)
	1	Round meet table
	2	meet chairs
	2	under file cab

22-09	1	Desk setup (2 piece)
	1	Round meet table
	2	meet chairs
	2	under file cab
22-10	2	Desk Setups (1-1 piece and 1-2 piece)
	2	Task chairs
	2	under file cab
22-11 (Neil Armstrong)	2	Meeting Chairs
	1	Meet Table
Main Office Area	46	Cubicles
	46	Comp Arms
	46	Task Chairs
	46	under file cab
22-14 (Jaques Costeau)	1	Conf Table
	6	meeting chair
	1	TV
22-15	2	Desk Setups (2 piece)
	2	task chairs
	2	under file cab
22-16	2	Desk Setups (2 piece)
	2	task chairs
	2	under file cab
22-17	2	desk set up (2 piece)
	2	task chairs
	2	under file cab
22-18	2	desk set up (2 piece)
	2	task chair
	2	under file cab
22-19	1	Desk setp (lg)
	1	task chair
	1	under file cab

	1	Round meeting table
	2	meet chairs
	1	extra file cab
22-21	2	desk set up (2 piece)
	2	task chair
	2	under file cab
22-22	2	desk set up (2 piece)
	2	task chair
	2	under file cab
22-23 mothers room		empty
22-26 Thurgood Marshall	1	Conference Table
	1	TV
	10	Conf Chairs
22-27	2	desk set up (1 piece)
	2	task chair
	2	under file cab
	1	lg bookshelf
22-28	2	desk set up (1 piece)
	2	task chair
	2	under file cab
	1	lg bookshelf
LAB AREA		
22-31		empty
22-32		empty
22-33		empty
22-34		empty
22-35	1	6ft table
	2	6ft table/w shelf
22-37		empty
22-38	1	6ft table/w shelf
22-39	1	6ft table/w shelf
22-40	1	6ft table
	3	6ft table/w shelf

22-41 Formulations	9	6ft table
	9	6ft table/w shelf
	1	8ft table
	1	4ft table
	8	Lab Chair
	9	Lab Stool

Current Location (Room)	Final Location (Room)	Department	Equip. Type	Vendor/Model	Equip. ID
22-41	Storage	Formulations	Anaerobic Chamber	Coy Instruments	Chamber 19 to move to GMP Suite
22-41	Storage	Formulations	BSC Cabinet	ThermoFisher	10500
22-41	Storage	Formulations	BSC Cabinet	ThermoFisher	10501
22-41	Storage	Formulations	BSC Cabinet	ThermoFisher	10502
22-41	Storage	Formulations	BSC Cabinet	ThermoFisher	10503
22-41	Storage	Formulations	Microscope	Microscope	
22-41	Storage	Formulations	bilister pack TC benchtop	Sepha	
22-41	Storage	Formulations	centrifuge	Eppendorf	
22-41	Storage	Formulations	Iyotherm CFS1200		
22-41	Storage	Formulations	Encapsulator	Siemens	
22-41	Storage	Formulations	Anerobic Chamber	Coy Labs	Move to GMP Suite
22-41	Storage	Formulations	-20c Freezer		
22-35	TBD	I.O	BSC Cabinet	ThermoFisher	10424
22-32	TBD	I.O	BSC Cabinet	ThermoFisher	10450
22-32	TBD	I.O	BSC Cabinet	ThermoFisher	10449
22-32	TBD	I.O	BSC Cabinet	ThermoFisher	10442
22-35	Storage	I.O	Cell Sorter	BioRad	S3e
22-32	Storage	Mol. Tech	-20ºC Freezer	-20ºC EPPENDORF	
22-35	Storage	Mol. Tech	Centrifuge	MINISPIN OHAUS	5452EO686559
22-34	Storage	Mol. Tech	Minifuge	FRONTIER 5306	
22-34	Storage	Mol. Tech	PCR Hood	My-PCR workstation	MY-PCR32
22-32	Storage	Mol. Tech	Digital Heat Block	VWR	150108016
22-32	Storage	Mol. Tech	Microscope		
22-32	Storage	Mol. Tech	Heat Lamp	Fisher	
22-34	Storage	Mol. Tech	Tall Fridge	4ºC	
22-39	TBD	Mol. Tech	BSC Cabinet	ThermoFisher	10102
22-39	TBD	Mol. Tech	BSC Cabinet	ThermoFisher	10473
22-36	TBD	Mol. Tech	BSC Cabinet	ThermoFisher	10498
22-37	TBD	Mol. Tech	BSC Cabinet	ThermoFisher	10446
22-40	TBD	Mol. Tech	BSC Cabinet	ThermoFisher	10484

ARTWORK AS OF THE DATE OF THE SUBLEASE

2nd Floor Artwork

“Boston Rooftops” by Jodie Baehre (1 of 2)

“Boston Rooftops” by Jodie Baehre (1 of 2)

“Feeling Yellow” by Ricardo Maldonado

“Aerial” by Adam O’day

“Cape Cod” by Fletcher Boland

“The Landscape of Mt Auburn Cemetery” by Matthew Brown

“Maui Rainbow” by Danny Anderson

“Bass Harbor Light” by Matthew Brown

“Ocean of the Universe” by Aeropagita V

“Wisdom Talk” by Kevin Lange”

“Back Bay” by Judy Baehre

“South Station T” by Judy Baehre

“Piccasso Morning” by Emily Stauring

“Cape Cod” by Jennifer Carland

“Tango in the Piazza” by Christopher Clark

“Rite of Spring VI” by Sean Wright

“Marine Flecks” by Mary Sullivan

“Life Unfinished” by Kelly Lynn Kimball

“Intoxication” by Ben Kelley

“Floral Fireworks” by Regina Valluzzi

“Steak Burger” by Joe Carlton

? “March Spring” by Tamara Gonda”

“Oaxacan Bug Experiment” by Adam Rose

“Wanabi” by Jane Sullivan Fowler

“Shackleford Wild Horses” by Brad Styron

“They Break and they Bend” by Tamara Gonda

“Breezy Island Life” by Adam Romanowicz

“Red Balloons at Trocadero” by Julia Willard

“Ghosts in the Bean” by Adam Romanowicz

“Henry Wadsworth” by Matt Hodgson

“Portland Shine” by Emily Stauring

Exhibit 31.1

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 5, 2019

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

Exhibit 31.2

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 5, 2019

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

Exhibit 32.1

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

(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, 2019 (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 5, 2019

/s/ Eric D. Shaff
Eric D. Shaff
President and Chief Executive Officer

Exhibit 32.2

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

I, Marcus Chapman, 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, 2019 (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 5, 2019

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