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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2018

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 001-38356

MENLO THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**45-3757789**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

200 Cardinal Way, 2nd Floor

Redwood City, California 94063

(Address of principal executive offices including zip code)

650-486-1416

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
Emerging growth	☒		

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 12b-2 of the Act).

Yes ☐ No ☒

As of November 1, 2018, there were 23,232,184 shares of the registrant's Common Stock, par value $0.0001 per share, outstanding.

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This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are statements that could be deemed forward-looking statements reflecting the current beliefs and expectations of management with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other 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 these forward-looking statements. These statements are often identified by the use of words such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," "until," "if" and similar expressions or variations.

The following factors, among others, including those described in the section titled "Risk Factors" included in this Quarterly Report on Form 10-Q, could cause our future results to differ materially from those expressed in the forward-looking information:

- our clinical and regulatory development plans for serlopitant, including the timing of the commencement of, and receipt of results from, our ongoing and planned Phase 2 and Phase 3 clinical trials and the timing of our submission of an NDA to the FDA for serlopitant;
- our expectations regarding the potential safety and efficacy of serlopitant;
- our expectations regarding the potential market size and size of the potential patient populations for serlopitant, if approved or cleared for commercial use;
- the timing of commencement of future non-clinical studies and clinical trials;
- our ability to successfully complete clinical trials;
- our intentions and our ability to establish collaborations or obtain additional funding;
- our use of net proceeds from our initial public offering;
- the timing or likelihood of regulatory filings and approvals or clearances for our product candidates;
- our commercialization, marketing and manufacturing capabilities and expectations;
- our intentions with respect to the commercialization of serlopitant or any other candidates;
- the pricing and reimbursement of serlopitant, if approved;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, including the projected terms of patent protection;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations;
- our financial performance; and
- developments and projections relating to our competitors and our industry, including competing drugs and therapies.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Quarterly Report on Form 10-Q. Forward-looking statements involve known and unknown risks, uncertainties and other 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. We discuss these risks in greater detail in "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Quarterly Report on Form 10-Q. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PART I – FINANCIAL INFORMATION

Item 1. Unaudited condensed Financial Statements

Menlo Therapeutics Inc.
Condensed Balance Sheets
(in thousands, except share and per share data)

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,196	$ 10,206
Short-term investments	82,461	49,295
Accounts receivable	—	786
Prepaid expenses and other current assets	1,811	3,574
Total current assets	154,468	63,861
Long-term investments	—	2,978
Property and equipment, net	136	28
Other long-term assets	354	—
Total assets	$ 154,958	$ 66,867
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 2,702	$ 2,462
Accrued expenses and other current liabilities	5,360	3,559
Deferred revenue, current	—	1,796
Total current liabilities	8,062	7,817
Deferred revenue, long-term	—	6,735
Other non-current liabilities	12	22
Total liabilities	8,074	14,574
Commitments and contingencies (see Note 7)		
Series A convertible preferred stock, $0.001 par value, no shares and 14,300 shares authorized at September 30, 2018 and December 31, 2017, respectively; no shares and 14,300 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively; Liquidation value of $0 and $14,300 as of September 30, 2018 and December 31, 2017, respectively	—	14,183
Series B convertible preferred stock, $0.001 par value, no shares and 14,106,583 shares authorized at September 30, 2018 and December 31, 2017, respectively; no shares and 14,106,583 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively; Liquidation value of $0 and $45,000 as of September 30, 2018 and December 31, 2017, respectively	—	44,820
Series C convertible preferred stock, $0.001 par value, no shares and 14,201,878 shares authorized at September 30, 2018 and December 31, 2017, respectively; no shares and 11,854,463 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively; Liquidation value of $0 and $50,500 as of September 30, 2018 and December 31, 2017, respectively	—	50,324
Stockholders' equity (deficit):		
Preferred stock: $0.0001 par value; 20,000,000 shares and no shares authorized at September 30, 2018 and December 2017, respectively; no shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock: $0.0001 par value; 300,000,000 shares and 55,000,000 shares authorized at September 30, 2018 and December 31, 2017, respectively; 23,232,184 and 5,298,593 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	3	1
Additional paid-in capital	240,024	2,207
Accumulated other comprehensive loss	(101)	(51)
Accumulated deficit	(93,042)	(59,191)
Total stockholders' equity (deficit)	146,884	(57,034)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 154,958	$ 66,867

See accompanying notes.

Menlo Therapeutics Inc.
Condensed 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,	
	2018	2017	2018	2017
Collaboration and license revenue	$ —	$ 909	$ 10,640	$ 1,807
Operating expenses:				
Research and development	10,667	8,008	37,913	18,461
General and administrative	3,035	1,236	8,822	3,462
Total operating expenses	13,702	9,244	46,735	21,923
Loss from operations	(13,702)	(8,335)	(36,095)	(20,116)
Interest income and other expense, net	855	163	2,243	316
Net loss attributable to common stockholders	$ (12,847)	$ (8,172)	$ (33,852)	$ (19,800)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	48	(19)	(50)	11
Comprehensive loss	$ (12,799)	$ (8,191)	$ (33,902)	$ (19,789)
Net loss attributable to common stockholders per share, basic and diluted	$ (0.56)	$ (1.60)	$ (1.60)	$ (3.89)
Weighted-average number of common shares used to compute basic and diluted net loss per share	22,977,793	5,116,165	21,164,069	5,093,418

See accompanying notes.

Menlo Therapeutics Inc.
Condensed Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2018	**2017**
Operating activities		
Net loss	$ (33,852)	$ (19,800)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	10	5
Amortization of premium on investment securities	(551)	73
Stock-based compensation expense	2,564	1,217
Disposal of equipment	—	19
Change in operating assets and liabilities:		
Accounts receivable	786	(460)
Prepaid expenses and other current assets	1,763	(1,143)
Other long-term assets	(354)	66
Accounts payable	240	2,001
Accrued expenses and other current liabilities	1,819	1,320
Deferred revenue	(8,531)	(1,347)
Other non-current liabilities	(10)	(16)
Net cash used in operating activities	(36,116)	(18,065)
Investing activities		
Purchase of property plant and equipment	(118)	(15)
Purchase of investments	(109,952)	(59,171)
Proceeds from sales of investments	5,100	6,000
Proceeds from maturities of investments	75,165	31,821
Net cash used in investing activities	(29,805)	(21,365)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	125,417	50,327
Proceeds from the exercise of stock options	494	34
Net cash provided by financing activities	125,911	50,361
Net increase in cash and cash equivalents	59,990	10,931
Cash and cash equivalents at beginning of period	10,206	4,027
Cash and cash equivalents at end of period	$ 70,196	$ 14,958
Non-cash financing activities		
Conversion of preferred stock to common stock	$ 109,327	$ —

See accompanying notes.

Menlo Therapeutics Inc.
Notes to Unaudited Interim Condensed Financial Statements

1. Formation and Business of the Company

Menlo Therapeutics Inc. (the "Company") is a late-stage biopharmaceutical company focused on the development and commercialization of serlopitant for the treatment of pruritus, or itch, associated with various conditions such as prurigo nodularis, psoriasis and chronic pruritus of unknown origin. The Company believes that its product candidate, serlopitant, a highly selective once-daily, oral small molecule inhibitor of the neurokinin 1, or NK1 receptor, has the potential to significantly alleviate pruritus.

The Company was incorporated in Delaware in October 2011. Since commencing operations, the Company has devoted substantially all of its resources to developing its product candidate, serlopitant, including conducting clinical trials and providing general and administrative support for these operations.

Initial Public Offering

In January 2018, the Company completed its initial public offering ("IPO") of shares of its common stock, pursuant to which the Company issued 8,050,000 shares of common stock, which includes 1,050,000 shares issued pursuant to the underwriter's option to purchase additional shares, and received net proceeds of approximately $125.4 million, after deducting underwriting discounts, commissions and offering expenses. In connection with the completion of the Company's IPO, all shares of convertible preferred stock converted into 9,629,405 shares of common stock.

Liquidity and Capital Resources

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. Since inception, the Company has incurred losses and negative cash flows from operations. For the nine months ended September 30, 2018, the Company incurred a net loss of $33.9 million and used $36.1 million of cash in operations. As of September 30, 2018, the Company had cash, cash equivalents and investments of $152.7 million and an accumulated deficit of $93.0 million.

Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. Management plans to finance operations through equity or debt financings or other capital sources, including potential collaborations or other strategic transactions. There can be no assurances that, in the event that the Company requires additional financing, such financing will be available on terms which are favorable to the Company, or at all. If the Company is unable to raise additional funding to meet its working capital needs in the future, it will be forced to delay or reduce the scope of its research programs and/or limit or cease its operations.

The Company believes that its existing cash, cash equivalents and investments as of September 30, 2018 will provide sufficient funds to enable it to meet its obligations for at least the next 12 months from the issuance of our financial statements as of and for the nine months ended September 30, 2018.

2. Significant Accounting Policies

Basis of Presentation

The accompanying financial information for the three and nine months ended September 30, 2018 and 2017 is unaudited. These unaudited interim condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. In management's opinion, the unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, and include all adjustments, which include only normal and recurring adjustments necessary for the fair presentation of the Company's statement of financial position as of September 30, 2018, its statements of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017 and its statements of cash flows for the nine months ended September 30, 2018 and 2017. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results expected for the full fiscal year or any other period(s). The financial statements and related disclosures have been prepared with the presumption that users of the interim financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and notes thereto contained in the Company's Form 10-K for the year ended December 31, 2017, as filed with the SEC on March 28, 2018.

Reverse Stock Split

On January 8, 2018, the Company effected a reverse split of shares of the Company's common stock at a ratio of 1-for-2.6975 pursuant to an amendment to the amended and restated certificate of incorporation approved by the Company's board of directors and stockholders. The par value and the authorized shares of the common stock were not adjusted as a result of the reverse split. All issued and outstanding common stock share and per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse split for all periods presented, and the conversion ratio of the preferred stock was adjusted accordingly.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. All long-lived assets are maintained in the United States of America.

Use of Estimates

Preparation of financial statements in conformity with U.S. GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting periods covered by the financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, stock-based compensation expense, the resolution of uncertain tax positions and valuation allowance and accruals for research and development costs. Management bases its estimates on historical experience on various assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

Research and Development Expenses

Research and development costs are expensed as incurred. Substantially all of the Company's research and development expenses consist of expenses incurred in connection with the development of serlopitant. These expenses include certain payroll and personnel expenses including stock-based compensation expense, consulting costs, contract manufacturing costs and fees paid to clinical research organizations, or CROs, to conduct research and development. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

The Company estimates non-clinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage non-clinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock-based awards made to employees, directors and non-employees, based on estimated fair values recognized using the straight-line method over the requisite service period.

The fair value of options to purchase common stock granted to employees is estimated on the grant date using the Black-Scholes option valuation model. The calculation of stock-based compensation expense requires that the Company make certain assumptions and judgments about a number of complex and subjective variables used in the Black-Scholes model, including the expected term, expected volatility of the underlying common stock, and risk-free interest rate. The Company accounts for options issued to non-employees using the Black-Scholes option valuation model and is measured and recognized as the stock options are earned.

Revenue Recognition

The Company records revenue based on a five-step model in accordance with Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers ("ASC 606"). For the Company's collaboration agreement, which is discussed further under Note 5, the Company identifies the performance obligations, determines the transaction price, allocates the contract transaction price to the performance obligations, and recognizes the revenue when (or as) the performance obligation is satisfied.

The Company identifies the performance obligations included within the agreement and evaluates which performance obligations are distinct. Upfront payments for licenses are evaluated to determine if the license is capable of being distinct from the obligations of the Company to participate on certain development and/or commercialization committees with the collaboration partners and supply manufactured drug product for clinical trials. For performance obligations that the Company satisfies over time, the Company utilizes the input method and revenue is recognized by consistently applying a method of measuring progress toward complete satisfaction of that performance obligation. The Company periodically reviews its estimated periods of performance based on the progress under each arrangement and accounts for the impact of any changes in estimated periods of performance on a prospective basis.

Milestone payments are a form of variable consideration as the payments are contingent upon achievement of a substantive event. Milestone payments are estimated and included in the transaction price when the Company determines that it is probable that there will not be a significant reversal of cumulative revenue recognized in future periods. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration or other revenues and earnings in the period of adjustment.

Research and development revenues and cost reimbursements are based upon negotiated rates for the Company's full-time employee equivalents ("FTE") and actual out-of-pocket costs. FTE rates are set based upon the Company's costs, and which the Company believes approximate fair value. None of the revenues recognized to date are refundable if the relevant research effort is not successful.

In accordance with ASC 606, the Company is required to adjust the transaction price for the effects of the time value of money if the timing of payments agreed to by the parties to the contract, explicitly or implicitly, provides the Company or its customer with a significant benefit of financing the transfer of goods or services. The Company concluded that its collaboration agreement did not contain a significant financing component because the payment structure of its agreements arise from reasons other than providing a significant benefit of financing.

Net Loss per Share of Common Stock

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, convertible preferred stock and common stock options are considered to be potentially dilutive securities. Because the Company has reported a net loss for the three and nine months ended September 30, 2018 and 2017, diluted net loss per common share is the same as basic net loss per common share for those periods.

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Numerator:				
Net loss attributable to common stockholders, basic and diluted	$ (12,847)	$ (8,172)	$ (33,852)	$ (19,800)
Denominator:				
Weighted-average common shares outstanding	23,063,757	5,283,282	21,269,957	5,281,144
Less: weighted-average common shares subject to repurchase	(85,964)	(167,117)	(105,888)	(187,726)
Weighted-average common shares used to compute basic and diluted net loss per share	22,977,793	5,116,165	21,164,069	5,093,418
Net loss per share attributable to common stockholders				
Basic and diluted	$ (0.56)	$ (1.60)	$ (1.60)	$ (3.89)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	September 30,	
	2018	2017
	(unaudited)	
Stock options outstanding	3,050,067	2,152,906
Outstanding common stock subject to repurchase	79,351	160,246
Shares issuable related to ESPP	59,735	—
Convertible preferred stock issuable upon conversion to common stock	—	9,629,405
Total	3,189,153	11,942,557

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes the revenue recognition requirements in ASC 605, *Revenue Recognition*. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In August 2015, FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which effectively delayed the adoption date by one year, to an effective date for public entities for annual and interim periods beginning after December 15, 2017. In March, April and May 2016, the FASB issued additional updates to the new revenue standard relating to reporting revenue on a gross versus net basis, identifying performance obligations and licensing arrangements, and narrow-scope improvements and practical expedients, respectively. The effective date of this additional update is the same as that of ASU 2014-09. The guidance permits the use of either a full retrospective or modified retrospective method on January 1, 2018. The Company adopted the standard using the full retrospective method. The effect of initially applying the new revenue standard was immaterial. Based on the evaluation of its current collaboration agreement and associated revenue streams, revenue will be recorded consistently under both the current and the new standard.

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, *Leases* (ASC 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases today. ASC 842 supersedes the previous leases standard, ASC 840 Leases. In August 2018, the FASB issued ASU 2018-11, *Targeted Improvements to ASC 842*, which provides a new transition option in which an entity initially applies ASU 2016-02 at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The standard is effective on January 1, 2019, with early adoption permitted. The Company is currently evaluating the effects, if any, that the adoption of this guidance will have on its financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments — Credit Losses — Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 changes the impairment model for most financial assets and certain other instruments. ASU 2016-13 is effective for annual and interim reporting periods beginning after December 15, 2019. The Company is in the process of evaluating the impact the adoption of this standard would have on its financial statements and disclosures.

In February 2018, the FASB issued ASU 2018-02, *Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* that would permit entities to make a one-time reclassification from accumulated other comprehensive income (AOCI) to retained earnings for the stranded tax effects resulting from the newly enacted corporate tax rates under the Tax Cuts and Jobs Act (the "Act"), effective for the year ended December 31, 2017. The amount of the reclassification is calculated on the basis of the difference between the historical tax rate and newly enacted tax rate. The standard is effective for interim and annual periods beginning after December 15, 2018 with early adoption permitted. The Company is currently assessing the impact of this standard on its financial statements and disclosures.

In June 2018, the FASB issued ASU 2018-07 *Improvements to Nonemployee Share-Based Payment Accounting (Topic 718)* that expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for certain exemptions specified in the amendment. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company is currently evaluating the impact of the guidance on its financial statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, *Disclosure Update and Simplification*, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. The Company is in the process of evaluating the impact of the final rule on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)* which changes the fair value measurement disclosure requirements of ASC 820. The guidance is effective for fiscal years beginning after December 15, 2019, including interim reporting periods within that fiscal year. Early adoption is permitted. The Company is evaluating the potential impact of this standard on its condensed consolidated financial statements and disclosures.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40)*, relating to a customer's accounting for implementation, set-up, and other upfront costs incurred in a cloud computing arrangement that is hosted by a vendor (i.e., a service contract). Under the new guidance, a customer will apply the same criteria for capitalizing implementation costs as it would for an arrangement that has a software license. The new guidance also prescribes the balance sheet, income statement, and cash flow classification of the capitalized implementation costs and related amortization expense, and requires additional quantitative and qualitative disclosures. The ASU is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early application is permitted. The Company can choose to adopt the new guidance (1) prospectively to eligible costs incurred on or after the date this guidance is first applied or (2) retrospectively. The Company is evaluating the impact, if any, that this pronouncement will have on our financial position and results of operations.

3. Cash Equivalents and Investments

At September 30, 2018 and December 31, 2017, the balance in the Company's accumulated other comprehensive income was comprised solely of activity related to the Company's available-for-sale securities. There were no realized gains or losses recognized on the sale or maturity of available-for-sale securities during the three and nine months ended September 30, 2018 and 2017 and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive income for the same periods. All of the Company's available-for-sale securities are subject to a periodic impairment review. The Company considers an investment security to be impaired when its fair value is less than its carrying cost, in which case the Company would further review the investment to determine whether it is other-than-temporarily impaired. When the Company evaluates an investment for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, intent to sell, and whether it is more likely than not the Company will be required to sell the investment before the recovery of its cost basis. If an investment is other-than-temporarily impaired, the Company writes it down through earnings to its impaired value and establishes that as a new cost basis for the investment. The Company did not identify any of its available-for-sale securities as other-than-temporarily impaired in any of the periods presented. As of September 30, 2018, no investment was in a continuous unrealized loss position for more than one year, the unrealized losses were not due to change in credit risk, and the Company believes that it is more likely than not the investments will be held until maturity.

The following table summarizes the available-for-sale securities (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
September 30, 2018 (unaudited)				
Money market funds	$ 9,850	$ —	$ —	$ 9,850
Corporate notes	31,749	—	(55)	31,694
Commercial paper	83,744	—	—	83,744
Asset backed securities	12,226	—	(28)	12,198
Government notes	12,448	—	(18)	12,430
Total	$ 150,017	$ —	$ (101)	$ 149,916

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
December 31, 2017:				
Money market funds	$ 8,685	$ —	$ —	$ 8,685
Corporate notes	46,133	—	(35)	46,098
Government notes	6,191	—	(16)	6,175
Total	$ 61,009	$ —	$ (51)	$ 60,958

4. Fair Value Measurements

The fair value of the Company's financial instruments reflects the amounts that the Company estimates it would receive in connection with the sale of an asset or pay in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1 – Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date;

Level 2 – Inputs other than quoted prices that are observable for the assets or liability either directly or indirectly, including inputs in markets that are not considered to be active;

Level 3 – Inputs that are unobservable.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value using Level 3 inputs. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the periods presented. A summary of the assets and liabilities carried at fair value in accordance with the hierarchy defined above is as follows (in thousands):

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
September 30, 2018 (unaudited)				
Assets:				
Money market funds	$ 9,850	$ —	$ —	$ 9,850
Corporate notes	—	31,694	—	31,694
Commercial paper	—	83,744	—	83,744
Asset backed securities	—	12,198	—	12,198
Government notes	—	12,430	—	12,430
Total assets	$ 9,850	$ 140,066	—	$ 149,916

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
December 31, 2017:				
Assets:				
Money market funds	$ 8,685	$ —	$ —	$ 8,685
Corporate notes	5,103	40,995	—	46,098
Government notes	6,175	—	—	6,175
Total assets	$ 19,963	$ 40,995	$ —	$ 60,958

The Company uses a market approach for determining the fair value of all its Level 1 and Level 2 money market funds and marketable securities. To value its money market funds, the Company values the funds at $1 stable net asset value, which is the market pricing convention for identical assets that the Company has the ability to access.

5. License Agreements

Merck License

In December 2012, the Company entered into an exclusive worldwide royalty free license agreement with Merck Sharp & Dohme Corp., (Merck) for exclusive worldwide rights for the development and commercialization of serlopitant and two other NK1-receptor antagonists in all human diseases, disorders or conditions, except for the treatment and prevention of nausea or vomiting. The Company paid Merck an upfront non-refundable non-creditable licensing fee of $1.0 million dollars and issued to Merck shares of its common stock. In addition, the Company has agreed to make aggregate payments of up to $25.0 million dollars upon the achievement of specified development and regulatory milestones.

In May 2018, the Company paid a $3.0 million milestone payment associated with the initiation of the Company's Phase 3 clinical program for pruritus associated with prurigo nodularis. Future milestone payments are considered a form of variable consideration and accrued for when the Company determines that it is probable that there will not be a significant reversal of the accrual in future periods.

JT Torii Collaboration Agreement

In August 2016, the Company entered into a license and collaboration agreement (the "Collaboration Agreement") with Japan Tobacco Inc. and Torii Pharmaceutical Co. Ltd. (together referred to as "JT Torii"). Under the Collaboration Agreement, the Company granted to JT Torii the rights to develop and commercialize products containing serlopitant in Japan, for the treatment of diseases and conditions other than nausea or vomiting. In exchange, JT Torii paid the Company an upfront, non-refundable payment of $11.0 million. In addition, the Company was entitled to receive aggregate payments of up to $28.0 million upon the achievement of specified development and regulatory milestones, and $15.0 million upon the achievement of a commercial milestone, as well as tiered royalties from the mid-single digits up to the mid-teens on sales of licensed products in Japan. The Company's performance obligations under the license agreement included the transfer of intellectual property rights in the form of licenses, obligations to participate on certain development and/or commercialization committees with the collaboration partners and supply manufactured drug product for clinical trials.

In the second quarter of 2018, JT Torii informed the Company that they decided to halt the Japanese Phase 2 clinical trial of serlopitant, following which the Company and JT Torii agreed to terminate the Collaboration Agreement. As a result, the Company has reacquired full ownership of the development and commercialization rights to serlopitant in Japan and accelerated recognition of the remaining deferred revenue of $8.1 million during the quarter. In the second quarter of 2018, the Company also earned and recognized a $2.0 million milestone payment related to JT Torii's receipt of investigational new drug application ("IND") enabling past clinical study reports delivered by the Company under the Collaboration Agreement.

Under the Collaboration Agreement, the Company was reimbursed by JT Torii for the non-commercial supplies of serlopitant at the same rate it was charged by the third-party manufacturer for such supplies, which price did not include a significant or incremental discount for JT Torii. The assessment of performance obligations required judgment in order to determine the allocation of revenue to each deliverable and the appropriate period of time over which the revenue should be recognized.

Under the Collaboration Agreement, the Company determined that the license was not distinct from the research and development services because JT Torii could not use the license with its available resources to obtain any economic value without the Company's participation. The license and the services were combined as one unit of accounting and upfront payments were recorded initially as deferred revenue in the balance sheet. Revenue was then recognized over an estimated performance period as performance of services was being completed. The Company recognized the upfront fee based on performance of the obligation using input method over the period of performance, which represented the estimated development period in the territories based on the initial development plan managed by the joint steering committee. The original term of the agreement was through the expiration of the patents associated with serlopitant.

Under the Collaboration Agreement, the Company was entitled to receive aggregate payments of up to $28.0 million upon the achievement of specified development and regulatory milestones, and $15.0 million upon the achievement of a commercial milestone. Two of the milestones, which amount to $2.0 million each, related to the preparation of an IND for submission to regulatory authorities in the territory were considered substantive given that they are triggered by the Company's performance relative to the achievement of pre-specified, "at risk" milestone events, including the submission of all completed trials clinical data packages and the validation of the manufacturing process.

On September 1, 2017, the Company entered into a new services agreement with JT Torii to provide research and development services, including regulatory, chemistry and manufacturing support and related materials that is distinct from the original Collaboration Agreement. The Company evaluated the new services agreement and determined that the research and materials delivered to JT Torii represented another contract that provides distinct goods and services to JT Torii. The fees received under the services agreement were recognized as and when such services were performed by the Company and JT Torii consumed the benefits of those services. During the three and nine months ended September 30, 2018, the Company recognized revenue of zero and $10.6 million, respectively in the statement of operations related to the services and collaboration agreement. The services agreement terminated upon the termination of the Collaboration Agreement.

6. Balance Sheets Components

Accrued Expenses and Other Current Liabilities

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

	September 30, 2018	December 31, 2017
	(unaudited)	
Accrued personnel expenses	$ 1,805	$ 1,108
Accrued clinical and development expenses	3,215	2,250
Other	340	201
Total	$ 5,360	$ 3,559

7. Commitments and Contingencies

Legal Matters

The Company's industry is characterized by frequent claims and litigation, including claims regarding intellectual property. As a result, the Company may be subject to various legal proceedings from time to time. The results of any future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors. Management is not aware of any material pending or threatened litigation.

Leases

The Company conducts its operations using leased office facilities. In April 2016, the Company entered into a lease agreement for its prior location. The twenty-six month lease, began in May 2016, and provided 4,000 square feet of office space in Menlo Park, California. Base annual rent was initially approximately $20,000 per month, with annual increases.

In September 2017, the Company entered into a lease agreement for its current location. The thirty-month lease, began on October 1, 2017 and provides approximately 14,000 square feet of office space in Redwood City, California. Base annual rent is approximately $55,000 per month with annual increases.

The Company recognizes rent expense on a straight-line basis over the respective lease period. Rent expense was $0.2 million and $0.6 million, respectively, for the three and nine months ended September 30, 2018 and $0.1 million and $0.2 million, respectively, for the three and nine months ended September 30, 2017. As of September 30, 2018, total future minimum lease payments under its operating leases are as follows (in thousands):

2018	$	168
2019		674
2020		173
Total future minimum lease payments	$	1,015

Indemnification

As permitted under Delaware law and in accordance with the Company's bylaws, the Company is required to indemnify its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The Company is also party to indemnification agreements with its directors. The Company believes the fair value of the indemnification rights and agreements is minimal. Accordingly, the Company has not recorded any liabilities for these indemnification rights and agreements as of September 30, 2018.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. Management is not currently aware of any matters that could have a material adverse effect on the financial position, results of operations, or cash flows of the Company.

8. Stockholders' Equity (Deficit)

Equity incentive plan

Under the Company's 2011 Stock Incentive Plan (the "2011 Plan"), the Company may grant options to purchase common stock, restricted stock awards, or directly issue shares of common stock to employees, directors and consultants of the Company. Under the 2011 Plan, options granted are exercisable over a maximum term of 10 years from the date of grant and generally vest over a period of four years. The Company adopted a 2018 Omnibus Incentive Plan (the "2018 Plan"), effective January 2018. The 2018 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units, dividend equivalent rights and other stock and cash-based awards (including annual cash incentives and long-term cash incentives). The Company has reserved 3,000,000 shares of common stock for issuance pursuant to awards under the 2018 Plan. As of September 30, 2018, the Company has 2,195,901 shares of common stock available for issuance under the 2018 Plan.

The Company adopted a 2018 Employee Stock Purchase Plan ("ESPP") in January 2018. The ESPP enables eligible employees of the Company and designated affiliates to purchase shares of common stock at a discount of 15%. Six month offer periods under the ESPP commenced on September 1, 2018. The Company has reserved 325,000 shares of common stock for issuance under the ESPP.

Total stock-based compensation expense for employees and non-employees recognized in the statements of operations was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Research and development	$ 475	$ 322	$ 1,217	$ 676
General and administrative	519	267	1,347	541
Total stock-based compensation expense	$ 994	$ 589	$ 2,564	$ 1,217

The table below summarizes stock option and restricted award activity under the 2011 and 2018 Plan:

	Number of Shares Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balances at December 31, 2017	2,506,926	$ 3.50	8.79	$ 24,033
Forfeited	(6,772)	$ 7.01		
Exercised	(254,186)	$ 1.94		1,786
Granted	804,099	$ 9.87		
Balances at September 30, 2018	3,050,067	$ 5.31	8.53	$ 14,880

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the condensed financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2017.

Overview

We are a late-stage biopharmaceutical company focused on the development and commercialization of serlopitant for the treatment of pruritus associated with various conditions such as prurigo nodularis, a severely pruritic skin condition with lesions, psoriasis and chronic pruritus of unknown origin. We believe that serlopitant, a highly selective small molecule inhibitor of the neurokinin 1, or NK1 receptor, has the potential to significantly alleviate pruritus.

We have initiated a broad clinical development program for serlopitant as a once-daily oral tablet treatment for pruritus. We have completed three double-blind Phase 2 clinical trials in over 850 patients with pruritus and observed clinically relevant and statistically significant improvements in pruritus in patients treated with serlopitant compared to patients treated with placebo in two of the three trials. The first Phase 2 clinical trial, conducted in 257 patients with chronic pruritus, met its primary and multiple secondary efficacy endpoints of pruritus reduction for patients treated at our two highest doses (5 mg and 1 mg daily) compared with those receiving placebo. The second Phase 2 clinical trial, conducted in 127 patients with prurigo nodularis, also met its primary and multiple secondary efficacy endpoints demonstrating significant pruritus reduction. In April 2018, we announced results from our third Phase 2 clinical trial, conducted in 484 patients with pruritus associated with atopic dermatitis. In this study, numerical differences favoring the serlopitant treated groups were evident at all timepoints, however, the study did not meet its primary and secondary efficacy endpoints, with no statistically significant difference demonstrated between the serlopitant treated groups and the placebo treated group. Serlopitant has been dosed in approximately 1,500 individuals and has been shown to be well tolerated, including when administered to patients in a clinical trial for up to one year.

Our current development program includes multiple ongoing and planned Phase 2 and pivotal Phase 3 clinical trials.

- We are currently enrolling two Phase 3 trials in patients with pruritus associated with prurigo nodularis with results from these trials expected in the first half of 2020. If these clinical trials are successful, we could potentially submit a New Drug Application, or NDA, in 2020.
- Our Phase 2 clinical trial in pruritus associated with psoriasis is fully enrolled, and we expect to report top-line data in December 2018.
- We plan to initiate a Phase 2 clinical trial in approximately 200 patients with chronic pruritus of unknown origin in the fourth quarter of 2018.
- We are currently enrolling a 52-week, multicenter, open-label safety study of serlopitant for the treatment of pruritus. The objective of this study is to provide long-term safety data for serlopitant in adults with pruritus associated with prurigo nodularis, atopic dermatitis, or psoriasis.

After the completion of our Phase 2 clinical trial in patients with pruritus associated with atopic dermatitis, we conducted retrospective analyses of our three Phase 2 pruritus clinical trials completed with serlopitant in an effort to understand further the atopic dermatitis clinical trial results and determine potential patient populations who may best respond to serlopitant therapy. All of these post hoc analyses were conducted solely for the purposes of informing future study design and indication selection, and do not constitute specific conclusions of efficacy. In these analyses, we observed several patterns that have informed our decision to initiate a clinical trial in patients with chronic pruritus of unknown origin. Our analyses suggested that patients without inflammatory skin disease appeared to respond better to serlopitant therapy than patients with inflammatory skin disease. Older patients or patients who had been pruritic for longer appeared to respond better to serlopitant therapy than patients who were younger or had a shorter duration of pruritus. We have modified the eligibility criteria in our Phase 3 prurigo nodularis clinical trials to exclude patients with active pruritic inflammatory skin disease other than prurigo nodularis. Our ongoing psoriasis clinical trial is limited to a population with no more than 10% body surface area coverage with psoriasis lesions.

In addition to the clinical trials we have conducted with serlopitant for the treatment of pruritus, we also conducted a Phase 2 clinical trial in 185 patients with refractory chronic cough. In October 2018, we announced top-line results from this study in which treatment with serlopitant failed to demonstrate benefit versus placebo on the primary and key secondary endpoints. Treatment related adverse events occurred at comparable rates in the serlopitant and placebo treated groups. Based upon the results of this trial, we do not anticipate further development of serlopitant for the treatment of refractory chronic cough.

Since commencing operations in 2011, we have devoted substantially all of our efforts and financial resources to the clinical development of serlopitant. We have not generated any revenue from product sales and, as a result, we have never been profitable and have incurred net losses in each year since commencement of our operations. As of September 30, 2018, we had an accumulated deficit of $93.0 million, primarily as a result of research and development and general and administrative expenses. We incurred net losses of approximately $33.9 million and $19.8 million for the nine months ended September 30, 2018 and 2017 , respectively. We do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize serlopitant for the treatment of pruritus associated with one or more various conditions and we can provide no assurance that we will ever generate significant revenue or profits.

As of September 30, 2018, our cash, cash equivalents and investments totaled $152.7 million. In January 2018, we completed our initial public offering. We sold 8,050,000 shares of our common stock and received cash proceeds of approximately $125.4 million, net of underwriting commissions and related expenses. We believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations for at least the next 12 months from the issuance of our financial statements as of and for the nine months ended September 30, 2018. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. See "— Liquidity and Capital Resources."

Components of Operating Results

Collaboration and License Revenue

We recognized revenue pursuant to our license and collaboration agreement, or Collaboration Agreement and our services agreement with Japan Tobacco Inc. and Torii Pharmaceutical Co. Ltd., together referred to as JT Torii, in connection with the clinical development and commercialization of products covered by the collaboration, including non-refundable upfront license fees, contingent consideration payments based on the achievement of defined collaboration milestones and royalties on sales of commercialized products.

Under the Collaboration Agreement, we granted to JT Torii the right to develop and commercialize products containing serlopitant in Japan, for the treatment of diseases and conditions other than nausea or vomiting. In exchange, JT Torii paid us an upfront, non-refundable payment of $11.0 million in August 2016. In addition, we were entitled to receive aggregate payments of up to $28.0 million upon the achievement of specified development of which, we earned and received $4.0 million and regulatory milestones, and $15.0 million upon the achievement of a commercial milestone, as well as tiered royalties from the mid-single digits up to the mid-teens on sales of licensed products in Japan.

Revenue from the upfront payment was being amortized over the period of performance of the Collaboration Agreement, the period which we expect to provide research and development services to JT Torii.

On September 1, 2017, we entered into a services agreement with JT Torii to provide research and development services, including regulatory, chemistry and manufacturing support and related materials, that is distinct from the original Collaboration Agreement. We evaluated the services agreement and determined that the research and materials delivered to JT Torii represented a separate contractual arrangement that provided standalone value to JT Torii. The fees received under the services agreement were recognized as and when such services were performed by us and JT Torii consumed the benefits of those services.

In the second quarter of 2018, JT Torii informed us that they decided to halt the Japanese Phase 2 clinical trial of serlopitant, following which we and JT Torii agreed to terminate the Collaboration Agreement. As a result, we accelerated recognition of the remaining deferred revenue balance of $8.1 million. In the second quarter of 2018, we also earned and recognized a $2.0 million milestone payment related to JT Torii's receipt of all of the IND-enabling past clinical study reports we delivered prior to the termination of the Collaboration Agreement.

Operating Expenses

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of serlopitant. These expenses include certain payroll and personnel expenses including stock-based compensation, consulting costs, contract manufacturing costs and fees paid to clinical research organizations or CROs to conduct certain research and development activities on our behalf. We do not allocate our costs by each indication for which we are developing serlopitant, as a significant amount of our development activities broadly support all indications. In addition, several of our departments support our serlopitant drug candidate development program and we do not identify internal costs for each potential indication. We also have not historically tracked costs incurred in connection with our agreements with JT Torii separately, and such amounts have been included in research and development expenses. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

We expense both internal and external research and development expenses as they are incurred. We are focusing substantially all of our resources and development efforts on the development of serlopitant. We expect our research and development expenses to increase during the next few years as we seek to complete our clinical program, pursue regulatory approval of serlopitant in the United States and prepare for a possible commercial launch of serlopitant. Predicting the timing or the final cost to complete our clinical program or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the U.S. Food and Drug Administration or FDA, or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if serlopitant will receive regulatory approval in the United States with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, including stock-based compensation, for personnel in executive, finance, business and corporate development, and other administrative functions, professional fees for legal, consulting, accounting services, rent and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher consulting, legal and accounting services associated with maintaining compliance with stock exchange listing and SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Interest Income and Other Expense, Net

Interest income consists primarily of interest earned on our investments in corporate notes, commercial paper, asset backed securities, and government agency notes.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Increase (Decrease)	2018	2017	Increase
Collaboration and license revenue	$ —	$ 909	$ (909)	$ 10,640	$ 1,807	$ 8,833
Operating expenses:						
Research and development	10,667	8,008	2,659	37,913	18,461	19,452
General and administrative	3,035	1,236	1,799	8,822	3,462	5,360
Loss from operations	(13,702)	(8,335)	(5,367)	(36,095)	(20,116)	(15,979)
Interest income and other expense, net	855	163	692	2,243	316	1,927
Net loss	$ (12,847)	$ (8,172)	$ (4,675)	$ (33,852)	$ (19,800)	$ (14,052)

Collaboration and License Revenue

Collaboration and license revenue for the three and nine months ended September 30, 2018 was zero and $10.6 million, respectively, compared to $0.9 million and $1.8 million for the corresponding periods in 2017. Collaboration and license revenue for the nine months ended September 30, 2018 primarily consisted of revenue we recognized during the period from the initial upfront payment of $11.0 million under the Collaboration Agreement with JT Torii. The increase in collaboration and license revenue was primarily due to the accelerated recognition of the initial upfront payment as a result of the termination of the Collaboration Agreement in June 2018 and a $2.0 million milestone payment related to completion of certain clinical study reports pursuant to the Collaboration Agreement prior to its termination.

Research and Development Expenses

Research and development expenses for the three and nine months ended September 30, 2018 increased to $10.7 million and $37.9 million, respectively, from $8.0 million and $18.5 million for the same periods in 2017. The increase was primarily due to an increase in clinical trial expenses, an increase in personnel expenses as a result of an increase in our employee headcount, and an increase in manufacturing expenses. In May 2018, we made a $3.0 million milestone payment to Merck associated with the initiation of our Phase 3 clinical trials for pruritus associated with prurigo nodularis. For the periods presented, substantially all of our research and development expenses are related to our development activity for serlopitant.

General and Administrative Expenses

General and administrative expenses for the three and nine months ended September 30, 2018 increased to $3.0 million and $8.8 million, respectively from $1.2 million and $3.5 million for the same periods in 2017. The increase was primarily due to an increase in professional fees as a result of becoming a public company as well as an increase in personnel expenses as a result of an increase in our employee headcount.

Interest Income and Other Expense, Net

Interest income and other expense, net for the three and nine months ended September 30, 2018 and 2017 primarily consisted of interest income generated from our cash, cash equivalents and investments.

Liquidity and Capital Resources

Through September 30, 2018, we have financed our operations primarily through the sale of equity securities and payments under the Collaboration Agreement. As of September 30, 2018, we had cash, cash equivalents and investments of $152.7 million. Our cash, cash equivalents and investments are held in money market accounts and investments in commercial paper, corporate notes, asset backed securities, and government notes. We believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations for at least the next 12 months from the issuance of our financial statements as of and for the nine months ended September 30, 2018. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

In January 2018, we completed our initial public offering. We sold 8,050,000 shares of our common stock and received cash proceeds of approximately $125.4 million, net of underwriting commissions and related expenses.

We expect to incur substantial expenditures in the foreseeable future as we advance serlopitant through clinical development, the regulatory approval process and, if approved, commercial launch activities. Specifically, in the near term, we expect to incur substantial expenses relating to our ongoing and planned clinical trials, the development and validation of our commercial manufacturing process for serlopitant, and other development activities including potentially commencing Phase 3 clinical trials for pruritus associated with psoriasis. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

We will continue to require substantial additional capital to develop our product candidate and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the time and cost necessary to complete our ongoing and planned clinical trials of serlopitant, as well as the success of such trials;
- the number, size, type and duration of any additional clinical trials or studies we may choose to initiate or that we may be required to complete prior to obtaining regulatory approval of serlopitant;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and comparable foreign regulatory authorities, including the potential by the FDA or comparable regulatory authorities to require that we perform more studies than those that we current expect, and the costs of post-marketing studies that could be required by regulatory authorities;
- the timing of the milestone payments we must make to Merck;

- the costs of preparing to manufacture serlopitant on a commercial scale;
- our ability to successfully commercialize serlopitant;
- the manufacturing, selling and marketing costs associated with serlopitant, including the cost and timing of forming and expanding our sales organization and marketing capabilities;
- the amount of sales and other revenues from serlopitant, including the sales price and the availability of adequate third-party reimbursement;
- the degree and rate of market acceptance of any products launched by us or our partners;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the progress, timing, scope and costs of our non-clinical studies and clinical trials, including the ability to enroll patients in a timely manner for potential future clinical trials;
- the time and cost necessary to respond to technological and market developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our need and ability to hire additional personnel;
- our decision to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements; and
- the emergence of competing technologies or other adverse market developments.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others, rights to serlopitant in certain territories or indications that we would prefer to develop and commercialize ourselves.

See "Risk Factors" for further information regarding the risks associated with our substantial capital requirements.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2018	**2017**
Net cash (used in) provided by:		
Operating activities	$ (36,116)	$ (18,065)
Investing activities	(29,805)	(21,365)
Financing activities	125,911	50,361
Net increase in cash	**$ 59,990**	**$ 10,931**

Cash Used in Operating Activities

Cash used in operating activities for the nine months ended September 30, 2018 was $36.1 million, primarily due to the net loss of $33.9 million, which amount was partially offset by stock-based compensation of $2.6 million and changes in operating assets and liabilities, including a decrease in deferred revenue of $8.5 million, an increase in accrued expenses and other current liabilities of $1.8 million, and a decrease in prepaid expenses and other current assets of $1.8 million. Cash used in operating activities for the nine months ended September 30, 2017 was primarily due to the net loss for the period of $19.8 million as well as non-cash stock-based compensation expense of $1.2 million, and was also affected by changes in operating assets and liabilities, including a decrease of $1.3 million in deferred revenue, an increase in prepaid expenses of $1.1 million and an increase in accounts receivable of $0.5 million, offset by an increase in accounts payable and accrued liabilities of $3.3 million.

Cash Used in Investing Activities

Cash used in investing activities for the nine months ended September 30, 2018 represented purchases of investments of $110.0 million, which amount was partially offset by proceeds received from maturities and sales of investments of $80.3 million. Cash provided by investing activities for the nine months ended September 30, 2017 represented purchases of investments of $59.2 million, offset by proceeds received from maturities and sales of investments of $37.8 million.

Cash Provided by Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2018 consisted of $125.4 million of net proceeds from our initial public offering and $0.5 million in proceeds from the exercise of stock options. During the nine months ended September 30, 2017 cash provided by financing activities was $50.4 million, consisting primarily of net proceeds from the sale of Series C convertible preferred stock.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of September 30, 2018 (in thousands):

	Payments due by period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Lease obligations, net	$ 670	$ 345	$ —	$ —	$ 1,015

In December 2012, we entered into an exclusive worldwide royalty-free license agreement with Merck for exclusive worldwide rights for the development and commercialization of serlopitant and two other NK1 receptor antagonists in all human diseases, disorders or conditions, except for the treatment and prevention of nausea or vomiting. We have agreed to make aggregate payments of up to $25.0 million dollars upon the achievement of specified development and regulatory milestones for serlopitant, of which, $3.0 million was paid in May 2018. However, because the achievement of these milestones is not fixed and determinable, such commitments have not been included on our balance sheet or in the Contractual Obligations and Commitments table above.

We enter into contracts in the normal course of business with CROs for clinical trials, non-clinical studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

While our significant accounting policies are described in the Notes to our financial statements, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Revenue Recognition

We record revenue based on a five-step model in accordance with Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers ("ASC 606"). For the Collaboration Agreement, we identify the performance obligations, determine the transaction price, allocate the contract transaction price to the performance obligations, and recognize the revenue when (or as) the performance obligation is satisfied.

We identify the performance obligations included within the agreement and evaluate which performance obligations are distinct. Upfront payments for licenses are evaluated to determine if the license is capable of being distinct from the obligations to participate on certain development and/or commercialization committees with the collaboration partners and supply manufactured drug product for clinical trials. For performance obligations that are satisfied over time, we utilize the input method and revenue is recognized by consistently applying a method of measuring progress toward complete satisfaction of that performance obligation. We periodically review our estimated periods of performance based on the progress under each arrangement and account for the impact of any changes in estimated periods of performance on a prospective basis.

Milestone payments are a form of variable consideration as the payments are contingent upon achievement of a substantive event. Milestone payments are estimated and included in the transaction price when we determine that it is probable that there will not be a significant reversal of cumulative revenue recognized in future periods.

Research and development revenues and cost reimbursements are based upon negotiated rates for our full-time employee equivalents ("FTE") and actual out-of-pocket costs. FTE rates are set based upon our costs, and which we believe approximate fair value. None of the revenues recognized to date are refundable if the relevant research effort is not successful.

Research and Development Expenses

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

We estimate non-clinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage non-clinical studies and clinical trials on our behalf. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Stock-Based Compensation Expense

We measure and recognize compensation expense for all stock-based awards made to employees, directors and non-employees, based on estimated fair values recognized using the straight-line method over the requisite service period.

The fair value of options to purchase common stock granted to employees is estimated on the grant date using the Black-Scholes option valuation model. The calculation of stock-based compensation expense requires us to make certain assumptions and judgments about a number of complex and subjective variables used in the Black-Scholes model, including the expected term, expected volatility of the underlying common stock, risk-free interest rate, as well as estimating future forfeitures of unvested stock options. To the extent actual forfeiture results differ from the estimates, the difference will be recorded as a cumulative adjustment in the period the estimates are revised. We account for options issued to non-employees using the Black-Scholes option valuation model and is measured and recognized as the stock options are earned.

Investment Securities

We have an investment policy which limits us to investing in highly rated corporate and government notes, and no individual investment may comprise more than 5% of the total portfolio.

We classify our investment securities as available-for-sale. Those investments with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments with maturities greater than 12 months at the date of purchase are considered long-term investments. Our investment securities classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of comprehensive income or loss.

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Premiums (discounts) are amortized (accreted) over the life of the related security as an adjustment to yield using the straight-line interest method. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of securities sold.

We determine the fair value of our assets and liabilities based on 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 maximize the use of observable inputs and minimize the use of unobservable inputs. We use a fair value hierarchy with three levels of inputs, of which the first two are considered observable and the last unobservable, to measure fair value:

Level 1—Quoted prices in active markets for identical assets or liabilities;

Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Indemnification

As permitted under Delaware law and in accordance with our bylaws, we are required to indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. We are also party to indemnification agreements with our directors. We believe the fair value of the indemnification rights and agreements is minimal. Accordingly, we have not recorded any liabilities for these indemnification rights and agreements as of September 30, 2018.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We chose to "opt out" of this provision and, as a result, we comply with new or revised accounting standards when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

Recently Issued and Adopted Accounting Pronouncements

See "Recent Accounting Pronouncements" in Note 2, "Significant Accounting Policies" in the Notes to Unaudited Interim Condensed Financial Statements for a discussion of recently adopted accounting pronouncements and accounting pronouncements not yet adopted, and their expected impact on our financial position and results of operations.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates or exchange rates. As of September 30, 2018, we had cash, cash equivalents and investments of $152.7 million, consisting of interest-bearing money market accounts and investments in corporate notes, commercial paper, asset backed securities, and government securities, which would be affected by changes in the general level of United States interest rates. However, due to the short-term maturities and the low-risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash, cash equivalents and investments. Our market risks have not changed materially from those disclosed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2017.

We do not believe that inflation, interest rate changes, or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive and financial officers, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018 our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting during the quarter ended September 30, 2018 identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act 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.

We are not currently a party to any material legal proceedings.

1A. Risk Factors.

Our business is subject to various risks and uncertainties, including those described below, that we believe apply to our business and the industry in which we operate. You should carefully consider these risks, as well as the other information in our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.

Risks Related to Our Financial Position and Capital Needs

We have a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur losses for the foreseeable future. Serlopitant is our only product candidate in clinical trials and we have had no commercial sales, which, together with our limited operating history, makes it difficult to assess our future viability.

We are a late-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused principally on developing serlopitant, which is our only product in development. We are not profitable and have incurred losses in each year since our inception in 2011. We have only a limited operating history upon which stockholders can evaluate our business and prospects. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. We have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss for the nine months ended September 30, 2018 and 2017 was approximately $33.9 million and $19.8 million, respectively. As of September 30, 2018, we had an accumulated deficit of $93.0 million. We expect to continue to incur losses for at least the next few years, and we anticipate these losses will increase as we continue our development, seek regulatory approval of, and, if approved, begin to commercialize serlopitant. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require substantial additional financing, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.

We have devoted substantially all of our financial resources and efforts to the development of serlopitant. As of September 30, 2018, we had capital resources consisting of cash, cash equivalents and investments of $152.7 million. We expect to incur substantial expenditures in the foreseeable future as we advance serlopitant through clinical development, the regulatory approval process and, if approved, commercial launch activities. In the near term, we expect to incur substantial expenses relating to our ongoing and planned clinical trials and the development and validation of our commercial manufacturing process for serlopitant. Furthermore, we expect to continue to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. We also expect to incur expenses related to the recruitment and retention of personnel, working capital and other general corporate purposes. We may incur additional expenses in connection with expanding our pipeline, including by pursuing additional indications for serlopitant or the in-license or acquisition of additional drug candidates or commercial products.

We believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations through at least the next 12 months from the issuance of our financial statements as of and for the nine months ended September 30, 2018. However, because the outcome of any clinical trial or regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and ultimate commercialization of serlopitant, nor the timing of such expenditures. Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity, debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or planned operations

The size and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the time and cost necessary to complete our ongoing and planned clinical trials of serlopitant, as well as the success of such trials;
- the number, size, type and duration of any additional clinical trials or studies we may choose to initiate or that we may be required to complete prior to obtaining regulatory approval of serlopitant;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and comparable foreign regulatory authorities, including the potential by the FDA or comparable regulatory authorities to require that we perform more studies than those that we currently expect, and the costs of post-marketing studies that could be required by regulatory authorities;
- the timing of the milestone payments we must make to Merck;
- the costs of preparing to manufacture serlopitant on a commercial scale;
- our ability to successfully commercialize serlopitant;
- the manufacturing, selling and marketing costs associated with serlopitant, including the cost and timing of forming and expanding our sales organization and marketing capabilities;
- the amount of sales and other revenues from serlopitant, including the sales price and the availability of adequate third-party reimbursement;
- the degree and rate of market acceptance of any products launched by us or our partners;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the progress, timing, scope and costs of our non-clinical studies and clinical trials, including the ability to enroll patients in a timely manner in potential future clinical trials;
- the time and cost necessary to respond to technological and market developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our need and ability to hire additional personnel;
- our decision and ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements; and
- the emergence of competing technologies or other adverse market developments.

We may opportunistically seek financing before capital is required, based upon factors such as the market value of our securities, investor interest in acquiring ownership in our company, prevailing capital market conditions and results of our operations. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate clinical trials or other development and commercialization activities for serlopitant.

Risks Related to Our Business

We are substantially dependent on the success of our sole product candidate, serlopitant.

To date, we have invested substantially all of our efforts and financial resources in the development of serlopitant, which is our sole product candidate in development. Our prospects, including our ability to finance our operations and generate revenue from product sales, currently depend entirely on the successful development and commercialization of serlopitant. The clinical and commercial success of serlopitant will depend on a number of factors, including the following:

- the timely completion of and results from our two ongoing Phase 3 clinical trials of serlopitant for the treatment of pruritus associated with prurigo nodularis;
- the timely completion of and results from our ongoing Phase 2 clinical trial of serlopitant for the treatment of pruritus associated with psoriasis;
- the timely initiation of and results from our planned Phase 2 clinical trial of serlopitant for the treatment of chronic pruritus of unknown origin;
- the initiation of and results from any Phase 3 clinical trials, if conducted, in pruritus associated with psoriasis or chronic pruritus of unknown origin;

- the FDA's requirements with regard to the number, design, size, conduct, or implementation of our planned and future clinical trials;
- the ability of our clinical trials to demonstrate serlopitant's safety and efficacy to the satisfaction of the FDA or foreign regulatory authorities;
- the timely completion and results of any additional clinical trials and non-clinical studies conducted to support the filing for regulatory approvals of serlopitant;
- whether we are required by the FDA or foreign regulatory authorities to conduct additional clinical trials prior to approval to market serlopitant for any indication;
- our ability to execute on our clinical trial plans and monitor the conduct of the studies by the contract research organizations, or CROs, and medical institutions;
- the prevalence, frequency and severity of adverse side effects of serlopitant;
- the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities for our target indications;
- our ability to raise sufficient additional capital to fund development, manufacturing and commercialization activities for serlopitant;
- our ability to successfully commercialize serlopitant, if approved for marketing and sale by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;
- the ability of our third-party manufacturers to manufacture sufficient quantities of serlopitant using appropriate processes at a cost appropriate for our stage of development;
- the ability of our third-party manufacturers to comply with current good manufacturing practices, or cGMP;
- achieving and maintaining compliance with all regulatory requirements applicable to serlopitant;
- our success in educating physicians and patients about the benefits, administration and use of serlopitant;
- the willingness of physicians and patients to utilize or adopt serlopitant;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- our ability to obtain and sustain an adequate level of reimbursement for serlopitant by third-party payors;
- the effectiveness of our own or any future strategic collaborators' marketing, sales and distribution strategy and operations;
- the filing, prosecution, defense and enforcement of patent claims and other intellectual property rights;
- a continued acceptable safety profile of serlopitant following approval; and
- emerging safety signals from other drugs generally perceived to be in the same drug class as serlopitant, including NK1 receptor antagonists.

Many of these factors are beyond our control. Accordingly, we cannot be certain that we will ever be able to generate revenue through the sale of serlopitant. If we are not successful in commercializing serlopitant, or are significantly delayed in doing so, our business will be materially harmed.

Clinical drug development involves a 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 serlopitant.

To gain approval to market a drug product such as serlopitant, we must provide the FDA and foreign regulatory authorities with non-clinical, clinical, and chemistry, manufacturing, and controls, or CMC, data that adequately demonstrates the safety and efficacy of the product for the intended indication applied for in the New Drug Application, or NDA, or other respective regulatory filing. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Further, although members of our management team have conducted clinical trials and obtained marketing approvals for product candidates in the past while employed at other companies, we as a company have not done so. As a result, such activities may require more time and cost than we anticipate.

Our business currently depends entirely on the successful development, regulatory approval and commercialization of serlopitant following completion of all required non-clinical and clinical trials, and generation of adequate CMC data. We initiated two multi-center placebo-controlled double-blind Phase 3 clinical trials of serlopitant for the treatment of pruritus associated with prurigo nodularis in 2018 and we initiated our Phase 2 clinical trial in patients with pruritus associated with psoriasis in 2017. We expect data from our Phase 2 clinical trial to be available in December 2018. We are also preparing to initiate a Phase 2 trial in patients with chronic pruritus of unknown origin in the fourth quarter of 2018. However, there can be no assurances that such clinical trials will be successful. For example, in 2018, our completed Phase 2 clinical trials of serlopitant for refractory chronic cough and for the treatment of pruritus in atopic dermatitis patients did not meet their primary or key secondary endpoints.

Development of serlopitant for use in pediatric patients may be a required element of our development program for some of our target indications. We are developing a pediatric plan for review with regulatory authorities in Europe and the United States, if required.

We may experience numerous unforeseen events during or as a result of our non-clinical studies and clinical trials that could delay or prevent our ability to receive marketing approval or commercialize serlopitant, 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;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects required for clinical trials of serlopitant 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 or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- serlopitant may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors and clinical trial sites may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements or a finding that the trial subjects are being exposed to unacceptable risks; and
- the supply or quality of serlopitant or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

Our business could be harmed if a clinical trial is delayed, suspended or terminated by us, by the institutional review boards of the institutions in which such trials are being conducted, by a data safety monitoring board, if any, for such trial or by the FDA or other regulatory authorities.

Authorities may impose such a clinical trial delay suspension or termination due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, resulting in the imposition of a clinical hold,
- unforeseen safety issues or adverse side effects,
- failure to demonstrate a benefit from using serlopitant,
- changes in governmental regulations or administrative actions; or
- lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of serlopitant, the commercial prospects of serlopitant will be harmed, and our ability to generate product revenues from serlopitant will be delayed. In addition, any delays in successfully completing our clinical trials will increase our costs, slow down our development of serlopitant and its approval process and jeopardize our ability to commence product sales and generate revenues, which may materially harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of serlopitant. If we are required to conduct additional clinical trials or other testing of serlopitant beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of serlopitant candidates or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for serlopitant;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the drug removed from the market after obtaining marketing approval.

Results obtained in non-clinical studies and clinical trials may not predict success in later clinical trials.

Success in non-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be certain that any of our current and planned Phase 2 and Phase 3 clinical trials or any other clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market serlopitant in any indication.

The primary efficacy analysis in our completed Phase 2 clinical trials of chronic pruritus and pruritus associated with prurigo nodularis was a statistically significant change in itch visual analogue scale, or VAS, from baseline compared to placebo measured at week six or eight. Based upon our interactions with the FDA, we will use a different efficacy analysis for our Phase 3 clinical trials, a 4-point responder rate on the worst-itch numeric rating scale, or WI-NRS. We analyzed 4-point responders in our chronic pruritus and prurigo nodularis Phase 2 clinical trials after the completion of the studies. The analyses of the percentage of patients with at least a 40 mm response in VAS, or a 4-point response on WI-NRS, were not pre-specified in our initial completed Phase 2 clinical trials' statistical analysis plans, and are thus considered post-hoc analyses. For these and other reasons, our Phase 2 clinical trials may not predict serlopitant's ability to demonstrate a statistically significant reduction in pruritus using this measure in Phase 3 clinical trials. It is also possible that the FDA or other regulatory agencies may require additional endpoints that are not currently included in our serlopitant clinical trials.

In our completed Phase 2 clinical trial of serlopitant for pruritus associated with prurigo nodularis, concomitant medications for treatment of pruritus other than loratadine or cetirizine were excluded. In our Phase 3 clinical trials for pruritus associated with prurigo nodularis, patients will be permitted to take certain additional medications that were not permitted in the Phase 2 clinical trial. The efficacy or safety of serlopitant when used with other agents in the Phase 3 clinical trials may differ from the Phase 2 clinical trial as a result of these additional medications. Phase 3 clinical trials with larger numbers of patients or longer durations of therapy may also reveal safety concerns that were not identified in earlier smaller or shorter trials.

We and other companies in the biopharmaceutical industry have frequently suffered significant setbacks in later clinical trials, even after achieving promising results in earlier non-clinical studies or clinical trials. For example, in 2018, our completed Phase 2 clinical trials of serlopitant for refractory chronic cough and for the treatment of pruritus in atopic dermatitis patients did not meet their primary or key secondary endpoints.

We have utilized retrospective data analyses to inform our decision to initiate a Phase 2 clinical trial for patients with chronic pruritus of unknown origin and to modify our Phase 3 prurigo nodularis trial eligibility criteria.

After the completion of our Phase 2 study in atopic dermatitis, which failed to meet its primary and secondary endpoints, we conducted retrospective analyses of our three Phase 2 pruritus studies completed with serlopitant in an effort to further understand the atopic dermatitis trial results and determine potential patient populations who may best respond to serlopitant therapy. In these analyses, we observed patterns that informed our decision to initiate a trial in patients with chronic pruritus of unknown origin and to modify eligibility criteria to exclude additional subjects from participation in our Phase 3 prurigo nodularis trials should they have active inflammatory skin disease other than prurigo nodularis. Our post hoc analyses were conducted solely for the limited purposes of informing future study design and indication selection, and do not constitute specific conclusions of efficacy, nor do these analyses indicate that our clinical trials will be successful in meeting their primary or secondary endpoints. Retrospective analysis of data is susceptible to bias in data selection, analysis, and interpretation.

Use of patient-reported outcome assessments, or PROs, in our clinical trials may delay or impair the development of serlopitant and/or adversely impact our clinical trials.

Due to the difficulty of objectively measuring pruritus, the assessment of pruritus in clinical trials typically involves the use of PROs. PROs have an important role in the development and regulatory approval of treatments for pruritus. PROs involve patients' subjective assessments of efficacy, and this subjectivity can increase the uncertainty of clinical trial outcomes assessing pruritus. Such assessments can be influenced by a number of factors and can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical trial, leading to high variability in PRO measurements.

The variability of PRO measures for itch and the high placebo response rates could adversely impact our serlopitant development program. PROs for itch assessment have historically been observed to have high placebo group response rates, including in some of our trials. For example, in our Phase 2 clinical trial in patients with chronic pruritus, patients receiving placebo reported a greater than 25% decrease from baseline in itch VAS scores. Variability in the placebo group response has adversely impacted clinical results of other therapies being tested for itch reduction, and could adversely impact our clinical trial results. The variability of a PRO measure may be greater than some measures used for clinical trial assessments, and that variability can complicate clinical trial design, adversely impact the ability of a study to show a statistically significant improvement, and generally adversely impact a clinical development program by introducing additional uncertainties.

It is also possible that the FDA may require changes in the PRO we are currently using or may indicate that the PRO we are using is not acceptable for demonstrating efficacy in pruritus reduction, potentially delaying clinical development of serlopitant, increasing our costs and making additional clinical trials necessary.

If we experience delays or difficulties in the enrollment of subjects in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of subjects. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population and the ability of clinical sites to successfully recruit and retain subjects in clinical trials. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. For example, we previously initiated a clinical trial of serlopitant to treat pruritus following burn injury but discontinued the trial due to lack of timely enrollment. Enrollment can also be affected by seasonality and other factors. We may not be able to initiate continue or complete clinical trials for certain indications, if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials in a timely manner. In particular, among our target indications, prurigo nodularis is a relatively rare condition, which may make the trials more difficult to conduct or may significantly extend the expense and duration of these trials.

We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the prevalence and incidence of the conditions being studied in the clinical trials;
- the perceived risks and benefits of serlopitant;

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications we are investigating;
- the efforts to facilitate timely enrollment in clinical trials;
- competition for patients from other clinical trials;
- the success of any advertising campaigns conducted to recruit subjects to enroll in clinical trials;
- the willingness of potential clinical trial subjects to provide informed consent to participate in the trial;
- the patient referral practices of physicians;
- the ability to monitor subjects adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective subjects.

Our inability to enroll a sufficient number of subjects for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our drug candidates or delays in regulatory filings and progression, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we rely on and expect to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we will have limited influence over their performance.

We rely on third parties to conduct our non-clinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize serlopitant or any future product candidates.

We do not have the ability to independently conduct non-clinical studies and clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs, to conduct non-clinical studies and clinical trials on our drug candidates. The third parties with whom we contract for execution of our non-clinical studies and clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs. These third parties may also have relationships with other commercial entities, some of which may compete with us. In some cases, these third parties could terminate their agreements with us without cause.

Although we rely on third parties to conduct our non-clinical studies and clinical trials, we remain responsible for ensuring that each of our non-clinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, including some regulations commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. In the past, we have experienced an issue of non-compliance with dosing among several patients at one of the clinical sites in one of our trials. We determined through analysis of the results of the trial and a comprehensive third-party audit that this single-site issue did not affect the results of that clinical trial.

In addition, the execution of non-clinical studies and clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, 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, which would have a material adverse effect on our business.

We rely completely on third-party suppliers to manufacture serlopitant, and we intend to continue to rely on third parties to produce non-clinical, clinical and commercial supplies of serlopitant.

We currently contract with one third party for the manufacture of serlopitant drug substance and another third party for serlopitant drug products for clinical trials, and we do not plan to acquire the infrastructure or internal capability to produce our non-clinical, clinical or commercial supplies of serlopitant. We anticipate that these third parties will have capacity to support commercial operations, but we do not have any formal agreements at this time to cover commercial production of serlopitant.

In order for us to obtain approval of serlopitant or any future product candidates, our contract manufacturers must, pursuant to inspections that would be conducted after we submit our NDA or relevant foreign regulatory submission, maintain a compliance status acceptable to the FDA and other comparable foreign regulatory agencies. We do not directly control the manufacturing of serlopitant, and we are completely dependent on our contract manufacturers for compliance with the cGMP requirements for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or foreign regulatory agencies, we will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory clearance of our contract manufacturers' facilities. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We and our third-party manufacturers continue to refine and improve the manufacturing process, certain aspects of which are complex and unique, and we may encounter difficulties with new or existing processes, particularly as we seek to significantly increase our capacity to commercialize serlopitant. Our reliance on contract manufacturers also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information.

As drug candidates are developed through non-clinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, methods of making drug formulations, and drug formulations, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our drug candidates and jeopardize our ability to commence sales and generate revenue.

Key manufacturing steps and materials used in our drug substance and in our drug product are provided by limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs.

Certain manufacturing steps and materials used in our serlopitant drug substance and in our serlopitant drug product are currently performed by or purchased from single outside sources. We may engage additional contract manufacturers for production of supplies of materials used in the manufacture of serlopitant and to participate in the manufacture of the drug substance or drug product.

The reliance on a limited number of suppliers could result in:

- delays associated with redesigning or revalidating a drug product or manufacturing process due to a failure to obtain a single source material from an existing validated supplier;
- an inability to obtain an adequate supply of required materials; and
- reduced control over pricing, quality and delivery time.

We have supply agreements in place for certain materials of our drug substance and drug products, but do not have in place long term supply agreements. Therefore, the supply of a particular material could be terminated at any time without penalty to the supplier. In addition, we may not be able to procure required materials from third-party suppliers at a quantity, quality and cost acceptable to us. Any interruption in the supply of single source material could cause us to seek alternative sources of supply or manufacture these materials internally. Furthermore, in some cases, we are relying on our third-party collaborators to procure supply of necessary materials. If the supply of any materials for serlopitant is interrupted, materials from alternative suppliers may not be available in sufficient volumes or at acceptable quality levels, or at acceptable cost within required timeframes, if at all, to meet our needs or those of our third-party collaborators. This could delay our ability to complete clinical trials and obtain approval for commercialization and marketing of our product candidates, causing us to incur additional costs, delay new product introductions, or lose sales, and could harm our reputation.

Investigator sponsored trials of serlopitant may produce results and safety signals that are beyond our control and impact our development and commercialization of serlopitant.

Serlopitant has been evaluated in a 14-patient exploratory investigator sponsored study at Stanford University as a potential treatment to reduce pruritus associated with epidermolysis bullosa, a rare primarily pediatric skin condition. We may in the future choose to permit the Stanford University investigator or other investigators to evaluate serlopitant or future product candidates in other investigator sponsored studies. These studies have the potential to result in unexpected or adverse clinical trial results, serious adverse events or the identification of other undesirable side effects, or unexpected characteristics of serlopitant or other product candidates, which could adversely impact our development programs.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell serlopitant, if approved, or any future product candidates or generate product revenue.

We currently do not have a sales organization. In order to commercialize serlopitant, if approved, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If serlopitant receives regulatory approval, we expect to establish a specialty sales organization with technical expertise and supporting distribution capabilities to commercialize it to dermatologists and possibly also to pediatricians and primary care physicians, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, provide adequate training to sales and marketing personnel, gain access to physicians or persuade adequate numbers of physicians to prescribe serlopitant, if approved, or any future drugs, and effectively manage a geographically dispersed sales and marketing team. Our efforts to commercialize serlopitant on our own may also be impacted by the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines, and any unforeseen costs and expenses associated with creating an independent sales and marketing organization. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products.

We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales organization and distribution systems or in lieu of our own sales organization and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize serlopitant. If we are not successful in commercializing serlopitant or any future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we would incur significant additional losses.

If we breach our license agreement for serlopitant, we could lose the ability to continue the development and commercialization of our product. Merck also retains rights to serlopitant in specific fields.

In December 2012, we entered into a license agreement with Merck to obtain exclusive worldwide rights to research, develop, manufacture, market and sell serlopitant, other than for the treatment or prevention of nausea and vomiting. This agreement requires us to use commercially reasonable efforts to develop and commercialize serlopitant, make timely milestone payments, provide certain information regarding our activities with respect to such products, maintain the confidentiality of information we receive from Merck and indemnify Merck with respect to our development and commercialization activities under the terms of the agreement.

If we fail to meet these obligations, Merck has the right to terminate our exclusive license and upon the effective date of such termination, has the right to re-obtain the licensed technology as well as aspects of any intellectual property controlled by us and developed during the period the agreement was in force that relate to the licensed technology. This means that Merck could effectively take control of the development and commercialization of serlopitant after an uncured, material breach of our license agreement by us. This would also be the case if we voluntarily terminate the agreement. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the patents licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the license could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for serlopitant.

Merck could also develop serlopitant for treatment of nausea or vomiting or license these rights to a third party. Development of serlopitant in other fields could increase the possibility of identification of adverse safety results that impact our development of serlopitant for pruritus associated with various conditions. In addition, if approved, commercialization of serlopitant in other fields could result in an increased threat of off-label use to compete with the sale of serlopitant to treat these indications.

Collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize serlopitant.

In June 2018, we agreed to terminate our license and collaboration agreement with JT Torii under which we had granted JT Torii the rights to develop and commercialize products containing serlopitant in Japan. We may seek additional collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of serlopitant in the future. We may enter into these arrangements on a selective basis, depending on the merits of retaining commercialization rights ourselves compared to entering into selective collaboration arrangements with pharmaceutical or biotechnology companies for serlopitant internationally and possibly also in the United States. However, there can be no assurance that any such collaboration arrangements will be successful.

In addition, the success of any future collaboration arrangements that we may enter into will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

When entering collaboration arrangements, we are subject to a number of risks, including:

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon products, repeat or conduct new clinical trials, require a new formulation of products for clinical testing, may decide not to pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- any safety issues or adverse side effects that result from trials conducted by a collaborator will adversely impact our ability to obtain regulatory approval for serlopitant or any other product we may develop in the future;
- any failure by a collaborator to demonstrate efficacy of serlopitant, or any potential future product candidate, in its clinical trials could decrease the perceived likelihood of success for our clinical trials;
- disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters may lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement;
- collaboration arrangements are complex and time consuming to negotiate, document and implement, and we may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements;
- collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party and any such termination or expiration would adversely affect us financially and could harm our business reputation;
- collaboration agreements may be terminated and, if terminated, may result in delays or the need for a new collaborator or additional capital to pursue further development or commercialization of serlopitant or other future product candidates in certain markets;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- terms of any collaborations or other arrangements that we may establish may not be favorable to us;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- we will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators;
- collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party and any such termination or expiration could adversely affect us financially and could harm our business reputation;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may own or co-own intellectual property covering products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations;
- collaborators' sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings;
- adverse regulatory determinations or other legal action may interfere with the ability of a collaborator to conduct clinical trials or other development activity;
- one or more collaborator may be subject to regulatory or legal action resulting from the failure to meet healthcare industry compliance requirements in the conduct of clinical trials or the promotion and sale of products; and
- collaboration arrangements could be adversely impacted by changes in collaborators' key management personnel and other personnel that are administering collaboration agreements.

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

The biopharmaceutical industry is intensely competitive and is subject to rapid and significant change. We face competition from other pharmaceutical and biotechnology companies, research institutions, and other organizations, particularly companies that develop and market pharmaceutical products for dermatologic conditions. Our commercial potential may be limited by other companies that develop and sell other novel products that are effective for our target indications, or that may be more effective, safer or cost less than serlopitant.

Although there are currently no approved drugs specifically indicated for pruritus associated with psoriasis or prurigo nodularis or for chronic pruritus of unknown origin, either in the United States or in Europe, we may face competition from those companies that are developing drugs specifically to treat pruritus associated with a variety of underlying dermatologic or systemic conditions, companies that are developing and marketing NK1 receptor antagonists for other conditions, that, when approved, could be used off-label to treat pruritus, and companies that currently market or are developing treatments intended directly to treat the underlying disease condition in psoriasis, or prurigo nodularis that have also been shown to have anti-pruritic effects.

We are aware of multiple companies developing drug candidates targeting pruritus as the primary outcome measure in clinical studies in the United States. Of these companies, Vanda Pharmaceuticals, Opko Health, and Nerre Therapeutics, are developing NK1 receptor antagonists for pruritus indications that may compete with serlopitant.

Even if serlopitant receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If serlopitant receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If serlopitant does not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of serlopitant, if approved for commercial sale, will depend on a number of factors, including:

- its efficacy, safety and potential advantages compared to alternative treatments;
- our ability to offer serlopitant for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- the risk that a competitor product may treat both the underlying condition and the associated pruritus;
- our ability to hire and retain a sales force in the United States;
- our ability to attract and retain potential commercialization collaborators in markets outside of the United States if we choose to do so;
- the strength of our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the willingness of patients to pay out of pocket for serlopitant to the extent it is not reimbursed by third-party payors;
- the prevalence and severity of any side effects; and
- any restrictions on the use of serlopitant together with other medications.

If coverage and adequate reimbursement from third-party payors are not available, it may make it difficult for us to sell serlopitant profitably.

Our ability to commercialize serlopitant successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors establish coverage and adequate reimbursement for it. Patients who are prescribed treatments for their conditions and providers furnishing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of serlopitant, once approved.

Significant uncertainty exists as to the coverage and reimbursement status of newly approved products. A trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services, including requiring companies to demonstrate the comparative effectiveness of a new therapy against other types of therapies that are available. The clinical trials we have conducted and plan to conduct on serlopitant test serlopitant's performance against a placebo. Third-party payors may request additional trials to demonstrate comparative effectiveness. Such trials would be expensive and time consuming, and the results are uncertain. As a result of these cost containment measures, coverage and reimbursement may not be available for serlopitant when it is approved for commercialization, and, even if available, the level of reimbursement may not be sufficient enough for successful commercialization of serlopitant or may significantly limit our revenue or profits, if any.

In the United States, private third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, no uniform policy for determining coverage and reimbursement for products exists among third-party payors and coverage and reimbursement can differ significantly from payor to payor. Each plan determines whether or not it will provide coverage, what amount it will pay, and with respect to pharmaceutical products, on what tier of its formulary such product will be placed. The position of a prescription drug on a formulary generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of a product by patients and physicians. Each plan may separately require us to provide scientific and clinical support for the use of our products and, as a result, the coverage determination process is often a time-consuming and costly process with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all. Our inability to obtain coverage and adequate reimbursement promptly from both government-funded and private payors for any approved products that we develop could significantly harm our operating results, our ability to raise capital needed to commercialize our product candidates and our overall financial condition.

Serlopitant may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval or result in significant negative consequences following marketing approval, if any. The number of patients exposed to serlopitant treatment and the average exposure time in the clinical development program may be inadequate to detect rare adverse events that may only be detected once serlopitant is administered to more patients and for greater periods of time.

Undesirable side effects caused by serlopitant could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Serlopitant has been dosed in approximately 1,500 individuals across multiple completed Phase 1 and Phase 2 clinical trials and has been shown to be well-tolerated, including when administered to patients in a clinical trial for up to one year, and in shorter trials at much higher doses than our current planned therapeutic dose. However, patients may experience adverse reactions when using serlopitant. The most commonly reported treatment-emergent adverse events across our completed Phase 2 clinical trials were urinary tract infection (5.1%, as compared to 3.0% for patients treated with placebo), nasopharyngitis (5.0%, as compared to 3.3% for patients treated with placebo), diarrhea (4.8%, as compared to 3.5% for patients treated with placebo) and headache (4.5% as compared to 6.5% for patients treated with placebo). Although we have not observed evidence of these adverse reactions causing a safety concern in our clinical programs, it is possible that the FDA may ask for additional data regarding any adverse events seen in our trials. Results of our future trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval for our product candidate for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, our patient population includes a substantial proportion of elderly participants, which may increase the risk of adverse events, related or unrelated to serlopitant during our clinical trials. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, we cannot be fully assured that rare and severe side effects of serlopitant may only be uncovered with a significantly larger number of patients exposed to the drug. If one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

We must successfully manage multiple complex clinical trials simultaneously while growing our business.

We currently have multiple ongoing and planned Phase 2 and Phase 3 clinical trials of serlopitant, an ongoing long term safety study of serlopitant and multiple planned Phase 1 clinical trials of serlopitant to support an NDA. If the results of our ongoing and planned Phase 2 clinical trials are promising, we plan to rapidly advance serlopitant into Phase 3 clinical trials for those indications. As of September 30, 2018, we had 44 employees. In order to manage our operations, clinical trials, regulatory filings, manufacturing and supply activities, marketing and commercialization activities for serlopitant or any future product candidates, we will need to continue to expand our managerial, operational, finance, systems, facilities and other resources. To effectively execute our strategy, we must:

- manage all of our clinical trials, which are being conducted at multiple trial sites globally through multiple third parties;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties;
- expand our general and administrative and sales and marketing organizations;
- identify, recruit, retain, incentivize and integrate additional employees; and
- continue to improve our operational, legal, financial and management controls, reporting systems and procedures.

Inability to effectively expand or manage our personnel and other resources, and complexities or unforeseen expenses or setbacks associated with managing our clinical trials and other activities, could delay or prevent completion of our planned clinical trials, the commercialization of serlopitant or any future product candidates, or the successful expansion of our product pipeline.

We are highly dependent on the services of our senior management and our ability to attract and retain qualified personnel.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified personnel. In particular, we are highly dependent upon our experienced senior management, including Steven Basta, Chief Executive Officer, Mary Spellman, M.D., Chief Medical Officer, Paul Kwon, M.D., Chief Scientific Officer, and Kristine Ball, Senior Vice President, Corporate Strategy and Chief Financial Officer. The loss of services of any of these individuals could materially adversely impact our ability to sustain or grow our operations.

We may not be successful in our efforts to obtain regulatory approval of serlopitant in multiple indications or at all.

We may seek approval for serlopitant for pruritus associated with one or more conditions. If our ongoing, planned and future clinical trials are successful, we could potentially submit an NDA in 2020. If our Phase 3 clinical trials of serlopitant for pruritus associated with prurigo nodularis and any Phase 3 clinical trials we may initiate for pruritus associated with psoriasis following the completion of our ongoing Phase 2 clinical trial are successfully completed, and such clinical trials demonstrate efficacy and safety of the same dosage form and route of administration of serlopitant in both pruritus indications at approximately the same time, we may seek FDA approval concurrently for the treatment of pruritus in prurigo nodularis and psoriasis. There can be no assurance that we will successfully initiate any Phase 3 clinical trials for pruritus associated with psoriasis, or that any of the Phase 3 clinical trials that we do initiate will be completed in time to permit this, or that the FDA will review or approve multiple indications simultaneously.

It is possible that our strategy of pursuing multiple indications may distribute our activities in a manner that is less advantageous than a strategy that may focus on fewer indications or a single indication. It is possible that the data from trials in multiple indications could adversely affect the regulatory review of serlopitant as compared with data from trials for a single indication. The FDA may not accept our submission for more than one pruritus indication in a single NDA application and we may not be able to seek approval of multiple indications for review at the same time, which could increase the time and expense required to obtain approval of multiple indications and delay the launch of one or more of our planned indications.

We may have chosen indications for serlopitant development that are more difficult or have less commercial potential than other possible indications.

Because we have limited financial and management resources, we are focusing on development programs for specific indications. As such, we are currently primarily focused on the development of serlopitant for the treatment of pruritus associated with various conditions. As a result, we may forego or delay pursuit of opportunities in other indications, or with other drug candidates that we may identify or that may be available, that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on profitable market opportunities. Our spending on current and future development programs and drug candidates for specific indications may not yield any commercially viable indication. If we do not accurately evaluate the commercial potential or target market for a particular indication for serlopitant, or for any other drug candidate, we may relinquish valuable rights to that drug candidate or indication through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

If we seek and obtain approval to commercialize serlopitant outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If serlopitant is approved for commercialization outside the United States, we may choose to commercialize it ourselves or enter into agreement with third parties to do so. If we chose to directly commercialize internationally, we expect that we will be subject to additional risks, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing United States and foreign drug import and export rules;
- different protection for intellectual property rights in foreign countries;
- different and additional regulatory requirements regarding data privacy (e.g. the EU General Data Protection Regulation);
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems, and different competitive drugs indicated to treat pruritus;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from development work conducted by these distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of serlopitant or any future product candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing of serlopitant in human clinical trials and will face an even greater risk if we sell commercially any drugs that we may develop. If we cannot successfully defend ourselves against claims that serlopitant causes injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- delays in clinical trials;
- decreased demand for serlopitant, if approved for marketing;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any drugs that we may develop.

We currently hold product liability insurance coverage in amounts that we believe are reasonable and customary for our industry and stage of development. This coverage 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 drug 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.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product and product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of

service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal, state and foreign privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws and the EU General Data Protection Regulation. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Risks Related to Our Intellectual Property

We may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development and commercialization of serlopitant or any future product candidates.

There have been many lawsuits and other proceedings asserting patents and other intellectual property rights in the pharmaceutical and biotechnology industries. We cannot assure you that serlopitant or any future product candidates will not infringe existing or future third-party patents. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be applications now pending of which we are unaware and which may later result in issued patents that we may infringe by commercializing serlopitant or future product candidates. Moreover, we may face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. We may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of serlopitant.

We may be subject to third-party claims in the future against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third-party's patents. We may be required to indemnify future collaborators against such claims. If a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. Even if we are successful in defending against such claims, such litigation can be expensive and time consuming to litigate and would divert management's attention from our core business. Any of these events could harm our business significantly.

In addition to infringement claims against us, if third parties prepare and file patent applications in the United States that also claim technology similar or identical to ours, we may have to participate in interference or derivation proceedings in the United States Patent and Trademark Office, or the USPTO, to determine which party is entitled to a patent on the disputed invention. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates.

If our intellectual property related to serlopitant or any future product candidates is not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to serlopitant and our development programs. Patents covering the composition of matter for serlopitant will expire in 2025, subject to potential extensions, where available, including, potential extension of up to five years in the United States. Patents and patent applications, if issued, covering methods-of-use for serlopitant to treat pruritus will expire in 2033 in the United States and 2034 in foreign countries. The expiration of our patents will limit our ability to profit from the commercialization of serlopitant. Furthermore, any disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in foreign countries. Even if patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the USPTO may be subject to third-party challenges such as (without limitation) re-examination proceedings, post-grant review, or *inter partes* review, and patents granted by the European Patent Office may be opposed by any person within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in some jurisdictions third parties can raise questions of validity with a patent office even before a patent has granted. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. For example, a third-party may develop a competitive product that provides therapeutic benefits similar to serlopitant but has a sufficiently different composition to fall outside the scope of our patent protection. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to serlopitant or any future product candidates is successfully challenged, then our ability to commercialize serlopitant or any future product candidates could be negatively affected, and we may face unexpected competition that could have a material adverse impact on our business. Further, if we encounter delays in our clinical trials, the period of time during which we could market serlopitant or any future product candidates under patent protection would be reduced.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or one of our future collaborators were to initiate legal proceedings against a third party to enforce a patent covering serlopitant or one of our future products, the defendant could counterclaim that our patent 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 could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. 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 against our intellectual property related to serlopitant, we would lose at least part, and perhaps all, of the patent protection on serlopitant. Such a loss of patent protection would have a material adverse impact on our business. Moreover, our competitors could counterclaim that we infringe their intellectual property, and some of our competitors have substantially greater intellectual property portfolios than we do.

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain and/or enforce and any other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and endeavor to execute confidentiality agreements with all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or who had access to our proprietary information, nor can we be certain that our agreements will not be breached. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do

not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

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 biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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 non-compliance with these requirements.

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. Noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We have not yet registered trademarks for a commercial trade name for serlopitant in the United States or elsewhere and failure to secure such registrations could adversely affect our business.

We have not yet registered trademarks for a commercial trade name for serlopitant in the United States or elsewhere. During trademark registration proceedings, our trademark application may be rejected. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties can oppose pending trademark applications and seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

We may not be able to enforce our intellectual property rights throughout the world.

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 life sciences. This could make it difficult for us to stop the infringement of our patents 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.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market serlopitant or any future products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We may not be able to protect our proprietary information and technology adequately. Although we use reasonable efforts to protect our proprietary information, technology, and know-how, our employees, consultants, contractors and outside scientific advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our proprietary information, technology or know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect proprietary information, technology and know-how. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants and other parties to protect our proprietary information, technology and know-how. These agreements may be breached, and we may not have adequate remedies for any breach. Moreover, others may independently develop similar or equivalent proprietary information, and third parties may otherwise gain access to our proprietary knowledge.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or 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 conceives or develops intellectual property that we regard as our own. Our 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.

Risks Related to Government Regulation

The regulatory approval process is lengthy, time-consuming, and highly uncertain, and we may experience significant delays and may not obtain regulatory approval for the commercialization of serlopitant or any future product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize serlopitant. Neither we nor any future collaborator is permitted to market serlopitant or any future product candidate in the United States or in any foreign countries until we or they receive approval of an NDA from the FDA or marketing authorization from the applicable regulatory authorities of such jurisdictions. We have not submitted an application or obtained marketing approval for serlopitant anywhere in the world. Obtaining regulatory approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable United States and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of regulatory approval of products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Prior to obtaining approval to commercialize a drug candidate in the United States or abroad, we or any future collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such drug candidate is safe and effective for its intended uses. The number of non-clinical studies and clinical trials that will be required for FDA approval varies depending on many factors, including the drug candidate, the disease or condition that the drug candidate is designed to address, and results of non-clinical studies and clinical trials of the drug candidate. Even if we believe the non-clinical or clinical data for our drug candidates is promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering drug candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a drug candidate for any or all targeted indications.

Regulatory approval of an NDA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process and we may encounter matters with the FDA that requires us to expend additional time and resources and delay or prevent the approval of our product candidates. For example, the FDA may require us to conduct additional studies or trials for serlopitant either prior to or post-approval, such as additional drug-drug interaction studies or safety or efficacy studies or trials, or it may object to elements of our clinical development program such as the number of subjects in our current clinical trials from the United States. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to, the following:

- a drug candidate may not be deemed safe or effective;
- FDA officials may not find the data from non-clinical studies and clinical trials sufficient;
- the FDA might not approve our third-party manufacturers' processes or may find objectionable conditions at our third-party manufacturers' facilities that must be corrected before our drug candidate can be approved; or
- the FDA may change its approval policies or adopt new regulations.

If serlopitant or any future product candidate fails to demonstrate safety and efficacy in clinical trials or does not gain regulatory approval, our business and results of operations will be materially and adversely harmed. Additionally, if the FDA requires that we conduct additional clinical studies, places limitations on serlopitant in our label, delays approval to market serlopitant or limits the use of serlopitant, our business and results of operations may be harmed.

Even if we receive regulatory approval of serlopitant or any future product candidates, the approval may be limited and we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals or other marketing authorizations we obtain for serlopitant or any future product candidates may be subject to limitations on the indicated uses for which the product may be marketed or the conditions of approval or marketing authorization, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority authorizes our product candidates for marketing, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and record keeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product, withdrawal of the product from the market, or product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to accept new marketing applications or supplements, approve or otherwise authorize for marketing pending applications or supplements to applications filed by us or current or future collaborators or suspension or revocation of approvals or other marketing authorizations;
- product seizure or detention, or refusal to permit the import or export of our product; and
- injunctions or the imposition of civil or criminal penalties.

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. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and devices and to spur innovation, but its ultimate implementation is unclear. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA's user fee programs and included additional drug and device provisions that build on the Cures Act. 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 not obtain marketing approval, or we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

On May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump 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 of marketing applications. It is difficult to predict how these or future executive actions 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.

We expect that any regulatory approval to market serlopitant in the United States will be limited by indication. If we fail to comply or are found to be in violation of FDA and other regulations restricting the promotion of serlopitant for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

If our clinical trials are successful, we intend to seek approval to market serlopitant for the treatment of pruritus associated with various specified conditions. If we obtain regulatory approval to market serlopitant with an indication statement for the treatment of one or more of these indications, we will likely be prohibited from marketing serlopitant using any promotional claims relating to treatment of pruritus generally. Marketing of serlopitant may also be limited by regulatory authorities based on use as a monotherapy or adjuvant, concomitant medications, severity of pruritus and other factors.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. Serlopitant may not be promoted for uses that are not approved in the labeling by the FDA or EMA. Physicians may, following FDA approval, nevertheless prescribe serlopitant off-label to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of serlopitant for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "*qui tam*" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a *qui tam* suit is entitled to a share of any recovery or settlement. *Qui tam* suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a *qui tam* suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

If approved, serlopitant or any future products may cause or contribute to adverse medical events that we are required to report to regulatory agencies and if we fail to do so we could be subject to sanctions that would materially harm our business.

If we are successful in commercializing serlopitant or any other products, FDA and foreign regulatory agency regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed time frame. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or a foreign regulatory agency could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.

Before our contract manufacturers can begin commercial manufacture of serlopitant, the process and systems used in the manufacture of serlopitant must be approved and each facility must have a compliance status that is acceptable to the FDA and other regulatory authorities. In addition, pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA and foreign regulatory authorities, before and after product approval. Due to the complexity of the processes used to manufacture pharmaceutical products and product candidates, any potential third-party manufacturer may be unable to continue to pass or initially pass federal, state or international regulatory inspections in a cost-effective manner. Furthermore, although we do not have day-to-day control over the operations of our contract manufacturers, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

If a third-party manufacturer with whom we contract is unable to comply with applicable laws and regulations, including cGMPs, serlopitant may not be approved, or we may be subject to fines, unanticipated compliance expenses, recall or seizure of our products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our financial results and financial condition.

Our failure to obtain regulatory approvals for serlopitant in foreign jurisdictions would prevent us from marketing our products in such jurisdictions.

In order to market any product in the European Economic Area, or EEA (which is composed of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), and many other foreign jurisdictions, separate regulatory approvals are required. In the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. Before granting the MA, the European Medicines Agency, or EMA, or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries 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. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not be able to file for regulatory approvals or to do so on a timely basis, and even if we do file we may not receive necessary approvals to commercialize our products in any market.

We may be subject to healthcare laws and regulations relating to our business, and could face substantial penalties if we are determined not to have fully complied with such laws, which would have an adverse impact on our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, customers and patients, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products for which we obtain marketing approval. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities 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 U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil 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 U.S. government, claims for payment or approval 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 U.S. government;
- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of HIPAA protected health information;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state and local laws requiring the registration of pharmaceutical sales representatives; and state and non-U.S. laws governing 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.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities may conclude that our business practices, including our consulting and advisory board arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could adversely affect our ability to operate our business and our results of 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 non-U.S. jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, 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.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act was enacted in the United States 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 healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on the pricing of medical items and services, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- 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 methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% beginning January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as efforts by the Trump administration to repeal and replace certain provisions of the Affordable Care Act. It is uncertain the extent to which any such changes may impact our business or financial condition.

Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act 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 Affordable Care Act 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." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." More recently, in July 2018, the Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. We continue to evaluate the potential impact of the Affordable Care Act and its possible repeal or replacement on our business. The current Administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes include the Budget Control Act of 2011, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, due to the subsequent legislative amendments, including under the BBA, and will remain in effect through 2027; the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years; and the Medicare Access and CHIP Reauthorization Act of 2015, which, among other things, ended the use of the sustainable growth rate formula and provides for a 0.5% update to physician payment rates for each calendar year through 2019, after which there will be a 0% annual update each year through 2025. In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and enacting federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products.

At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product and medical device pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in October 2017, California passed a new law, to become effective in January 2019, which will require transparency from biopharmaceutical companies regarding price increases for prescription drugs. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and medical devices to purchase and which suppliers will be included in their prescription drug and other healthcare programs.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved or cleared product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We face regulation and potential liability related to privacy, data protection and information security which may require significant resources and may adversely affect our business, operations and financial performance.

The regulatory environment surrounding privacy, data protection and information security is increasingly demanding. We are subject to numerous U.S. federal and state laws and non-U.S. regulations governing the protection of personal and confidential information of our clinical subjects, clinical investigators, employees and vendors/business contacts, including in relation to medical records, credit card data and financial information. Failure to comply with these data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business.

For example, HIPAA, as amended by HITECH, and their respective implementing regulations, impose specific requirements relating to the privacy, security and transmission of individually identifiable health information held by HIPAA "covered entities" and their "business associates". Among other things, HITECH made HIPAA's security standards directly applicable to HIPAA "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

Also, the European Parliament has adopted the General Data Protection Regulation, or the GDPR which become effective on May 25, 2018. This regulation replaced the EU's 1995 data protection directive and is the single EU standard across all member states. The GDPR takes a broad view of the types of information that are deemed covered as personal identification information and contains provisions that require businesses to protect such personal data and the privacy of EU citizens for transactions that occur within EU member states. The GDPR also regulates the exportation of personal data outside of the EU. Non-compliance with the GDPR could result in significant penalties. Our company is working with our contract research organizations and clinical trial sites in Europe to ensure compliance with this regulation.

Risks Related to Our Common Stock and Our Status as a Public Company

An active public market for our common stock may not be sustained.

We completed our initial public offering, or IPO in January 2018. Prior to that offering, there had been no public market for our common stock, and an active trading market for our shares may not be sustained. Further, certain of our existing institutional investors, including investors affiliated with certain of our directors, purchased an aggregate of 1,684,118 shares of common stock in our IPO. Accordingly, fewer shares may be actively traded in the public market because these stockholders will be restricted from selling the shares by restrictions under applicable securities laws, which would reduce the liquidity of the market for our common stock.

The lack of an active market may contribute to volatility of our stock price, impair our ability to raise capital and may impair our ability to acquire other businesses, applications or technologies using our shares as consideration.

The trading price of the shares of our common stock is volatile, and stockholders could incur substantial losses.

Our stock price is volatile. The stock market in general, and the market for 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, stockholders may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- announcement of clinical trial results or any other clinical data results we announce;
- the commencement or enrollment of our ongoing and planned clinical trials of serlopitant or any future clinical trials we may conduct, or changes in the development status of serlopitant;
- announcements of clinical trials results by competitors;
- adverse results from, delays in or termination of clinical trials;
- any delay in our regulatory filings for serlopitant or any other drug candidate and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse regulatory decisions, including failure to receive regulatory approval of our drug candidates;
- unanticipated serious safety concerns related to the use of serlopitant or any other drug candidate;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- future capital raising transactions;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that equity research analysts publish about us and our business. We do not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline. If our operating results fail to meet the forecast of analysts, our stock price will likely decline.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. In such a circumstance, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This 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 could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse in connection with our IPO, the market price of our common stock could decline significantly. The lock-up agreements pertaining to our IPO expired on July 23, 2018. As of September 30, 2018, there were approximately 23.2 million shares of our common stock outstanding. The lock-up expiration resulted in approximately 14.9 million additional shares of common stock becoming eligible for sale in the public market, approximately 11.0 million of which are held by current directors, executive officers and other affiliates and may be subject to sale in compliance with Rule 144 of the Securities Act.

In addition, approximately 5.3 million shares of common stock are either subject to outstanding options or reserved for future issuance under our equity incentive plans and will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of approximately 16.9 million shares of our common stock, or approximately 73.1% of our total outstanding common stock as of September 30, 2018, are entitled to certain rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

- 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 being able to fill 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 price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and 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 chief executive officer or 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 acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws, any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees.

Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, stockholders are not likely to receive any dividends on their common stock for the foreseeable future. Since we do not intend to pay dividends, stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

As of September 30, 2018, our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates will, in the aggregate, beneficially own 73.1% of our outstanding common stock.

As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that certain stockholders may believe are in their best interest.

We are an "emerging growth company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- 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 in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) December 31, 2023, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.07 billion, or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Commencing with our fiscal year ending December 31, 2018, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We have never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the Securities and Exchange Commission, or SEC, or other regulatory authorities.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2017, we had federal and state net operating loss carryforwards of $44.3 million and $15.0 million, respectively. These carryforwards will begin to expire in 2031 for federal and state purposes, if not utilized before they expire. As of December 31, 2017, we had federal and state research and development tax credit carryforwards of $2.1 million and $0.9 million, respectively. The federal credits begin to expire in 2031 and the California research credits have no expiration dates. These net operating loss and tax credit carryforwards could expire unused and be unavailable if we do not generate sufficient taxable income prior to their expiration. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change, by value, in its equity ownership by significant stockholders over a three-year period) the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or tax liability may be limited. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our net operating loss and tax credit carryforwards are subject to an annual limitation under Sections 382 or 383. We may have experienced ownership changes in the past, including in connection to our IPO, and we may experience ownership changes in the future as a result of any future offering and/or subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, even if we earn net taxable income, our ability to use our net operating loss and tax credit carryforwards may be materially limited, which could harm our future operating results by effectively increasing our future tax obligations.

Additionally, the Tax Cut and Jobs Act (the "Tax Act"), which was enacted on December 22, 2017, significantly reforms the Code, including changes to the rules governing net operating loss carryforwards. For net operating loss carryforwards arising in tax years beginning after December 31, 2017, the Tax Act limits a taxpayer's ability to utilize such carryforwards to 80% of taxable income. In addition, net operating loss carryforwards arising in tax years ending after December 31, 2017 can be carried forward indefinitely, but carryback is generally prohibited. Net operating loss carryforwards generated by us before January 1, 2018 will not be subject to the taxable income limitation and will continue to have a twenty-year carryforward period. However, the changes in the carryforward and carryback periods as well as the new limitation on use of net operating loss carryforwards may significantly impact our ability to use net operating loss carryforwards generated after December 31, 2017, as well as the timing of any such use, and could adversely affect our results of operations.

As a California-domiciled public company, we are required to bring a woman onto our board of directors by the end of 2019.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified individuals to our board of directors. As a public company headquartered in California, we are required to have at least one woman on our board of directors by the end of 2019, and two or three women on our board by the end of 2021, depending on the size of our board at the time. While we intend to comply with this California law, recruiting and retaining board members carries uncertainty, and failure to comply with this requirement will result in financial penalties.

We will incur increased costs and demands upon management as a result of being a new public company.

As a new public company listed in the United States, we incur significant additional legal, accounting and other costs, as compared to the costs we incurred as a private company. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the Nasdaq Stock Market, LLC, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

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

A) Recent sales of Unregistered Securities.

None.

B) Use of Proceeds from our Initial Public Offering of Common Stock

On January 24, 2018, our registration statement on Form S-1 (File No. 333-222324) relating to our IPO of common stock became effective. There has been no material change in the planned use of proceeds from our IPO as described in the Prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on January 26, 2018.

C) Repurchases of Shares or of Company Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The following documents are filed, or furnished as applicable, as part of this Quarterly Report on Form 10-Q:

Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	1/29/2018	3.1	
3.2	Amended and Restated Bylaws.	8-K	1/29/2018	3.2	
4.1	Reference is made to Exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	1/12/2018	4.2	
4.3	Second amended and Restated Investors' Rights Agreement, dated June 28, 2017, by and among the Company and the investors listed therein.	S-1	12/28/2017	4.3	
10.1#	Offer Letter, by and between the Registrant and Mary Spellman, effective as of July 21, 2017.				X
10.2#	Amendment No. 1 to Offer Letter, by and between the Registrant and Mary Spellman, effective as of April 22, 2018.				X
31.1	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).				X
31.2	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).				X
32.1*	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

# Denotes management contract or compensatory plan

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Menlo Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

Signatures

Pursuant to the requirements of Section 13 or 15(d) 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.

Dated: November 7, 2018

Menlo Therapeutics Inc.

By: /s/ Steven Basta
Steven Basta
President and Chief Executive Officer

By: /s/ Kristine Ball
Kristine Ball
Senior Vice President, Corporate Strategy and Chief Financial Officer

Exhibit 10.1

July 18, 2017

Dear Mary:

I am pleased to extend to you an offer of employment with Menlo Therapeutics Inc. (the "Company"), in the position of Senior Vice President, Clinical Development.

Salary: Your initial base salary will be $335,000 per year, less applicable withholdings. Your salary will be reviewed from time to time by the Board of Directors or its compensation committee, and may be adjusted in the sole discretion of the Board of Directors or its compensation committee.

Bonus: The Company will establish, in cooperation with you, objectives for your activities annually. The Company will evaluate your achievement of those objectives annually and you will be eligible for an annual bonus of up to 20% of your base salary.

Equity Award: After the start of your employment with the Company, the Board of Directors intends to grant you an option, in the amount of 250,000, to purchase shares of Common Stock of the Company. The exercise price of such option will be the fair market value of the Company's Common Stock on the date of grant, as determined by the Board of Directors based on an independent valuation intended to satisfy the safe harbor requirements of Section 409A of the Internal Revenue Code. The options shall vest with respect to 25% of the total number of shares on the one-year anniversary of your start date, and thereafter with respect to 1/48th of the total number of shares on each monthly anniversary of your start date. If, after a "change of control" transaction, as will be defined in your option agreement with the Company, you are terminated without Cause[1] or you terminate your employment for Good Reason[2], then vesting will accelerate with respect to 100% of the remaining unvested shares as of the date of termination. The option shall be subject to the terms and conditions of the Plan and the option agreement to be entered between you and the Company.

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1 For purposes of this paragraph, "Cause" means (i) your gross negligence or willful failure substantially to perform your duties and responsibilities to the Company or deliberate violation of a Company policy; your commission of any act of fraud, embezzlement or dishonesty against the Company or any other willful misconduct that has caused or is reasonably expected to result in material injury to the Company; your unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party to whom you owe an obligation of nondisclosure as a result of your relationship with the Company; or (iv) your willful breach of any of your obligations under any written agreement or covenant with the Company

2 For the purposes of this agreement, "Good Reason" means the occurrence at any time of any of the following without your prior written consent: (a) the material diminution in your authority, duties or responsibilities (other than a mere change in title following any merger or consolidation of the Company with another entity); (b) the assignment of duties or responsibilities materially inconsistent with those customarily associated with the position described in this offer letter or a material diminution of your position, authority, duties or responsibilities (other than a mere change in title following any merger or consolidation of the Company with another entity); (c) a material reduction in your base salary; (d) any willful failure or willful breach by the Company of any of the material obligations of this Agreement; or (e) a requirement that you relocate your principal place of business by more than fifty (50) miles. For purposes of this subsection, no act, or failure to act, on the Company's part shall be deemed "willful" unless done, or omitted to be done, by the Company not in good faith and without reasonable belief that the Company's act, or failure to act, was in the best interest of the Company. You may terminate your employment under this Agreement for Good Reason at any time on or prior to the 180th day after the initial occurrence of any of the foregoing Good Reason events; provided, however, that, within ninety (90) days of any such events having first occurred, you shall have provided the Company with notice that such event(s) have occurred and afforded the Company thirty (30) days to cure same.

Full Time and Attention: In this position you will dedicate your full business time and attention to the business of the Company. Except upon our prior written consent, you will not, during your employment with the Company, engage, directly or indirectly, in any other business activity (whether or not pursued for pecuniary advantage) that might interfere with your duties and responsibilities as a Company employee or create a conflict of interest with the Company. We acknowledge that you may for a limited period of time engage in certain activities associated with other consulting engagements previously committed by you to other parties. In order to fairly manage those, we will work with you to adjust your time (and pro-rata adjust compensation) for a reasonable period of time as may be requested by you to enable you to complete any such obligations.

At-Will Employment; Severance: The Company is an "at-will" employer. Accordingly, either you or the Company may terminate the employment relationship at any time, with or without advance notice, and with or without cause. Upon any termination of your employment, you will be deemed to have resigned. In the event the Company terminates your employment without Cause, or you terminate your employment for Good Reason, you will be eligible to receive an amount equal to six (6) months of your base salary ("Severance Benefits"). Your eligibility for this Severance Benefits is conditioned upon your execution of a release of claims in a form provided by the Company (the "Release") within forty-five (45) days following your termination date and non-revocation of the Release during any applicable statutory revocation period.

Taxes: All amounts paid under this letter shall be paid less all applicable state and federal tax withholdings (if any) and any other withholdings required by any applicable jurisdiction or authorized by you. Notwithstanding any other provision of this letter whatsoever, the Company, in its sole discretion, shall have the right to provide for the application and effects of Section 409A of the Code (relating to deferred compensation arrangements) and any related administrative guidance issued by the Internal Revenue Service. The Company shall have the authority to delay the payment of any amounts under this Agreement to the extent it deems necessary or appropriate to comply with Section 409A(a)(2)(B)(i) of the Code (relating to payments made to certain "key employees" of publicly-traded companies); in such event, any such amount to which you would otherwise be entitled during the six (6) month period immediately following your termination of employment with the Company will be paid in a lump sum on the date six (6) months and one (1) day following the date of your termination of employment with the Company (or the next business day if such date is not a business day), provided that you have complied with the requirements for such payment. You shall be treated as having a termination of employment under this Agreement only if such termination meets the requirements of a "separation from service" as that term is defined in Section 409A(a)(2)(A)(i) of the Internal Revenue Code of 1986, as amended (the "Code") and Treas. Regs. Section 1.409A-l(h), and as amplified by any other official guidance. This Agreement is intended to comply with the provisions of Code Section 409A; provided, however, that the Company makes no representation that the amounts payable under this Agreement will comply with Code Section 409A and makes no undertaking to prevent Code Section 409A from applying to amounts payable under this Agreement or to mitigate its effects on any deferrals or payments made under this Agreement.

In the event that the severance and other benefits provided for in this offer letter or otherwise payable to you (i) constitute "parachute payments" within the meaning of Section 280G of the Code, and (ii) but for this paragraph would be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then your benefits under this offer letter shall be either (a) delivered in full, or (b) delivered as to such lesser extent which would result in no portion of such benefits being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by you on an after-tax basis, of the greatest amount of benefits, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code.

Entire Agreement: Please let us know of your decision to join the Company by signing a copy of this offer letter and returning it to us not later than **July 21, 2017.** This letter sets forth our entire agreement and understanding regarding the terms of your employment with the Company and supersedes any prior representations or agreements, whether written or oral. This letter may not be modified in any way except in a writing signed by the Chief Executive Officer and you. It shall be governed by California law, without regard to principles of conflicts of laws. Your employment is contingent upon your execution of the Company's Proprietary Information and Invention Assignment Agreement.

We look forward to having you join us.

Sincerely,

/s/ Steven L. Basta

Steven L. Basta
Chief Executive Officer
Menlo Therapeutics

ACCEPTED AND AGREED:

/s/ Mary Spellman
_____
Mary Spellman, MD

July 21, 2017
_____
Date

Exhibit 10.2

AMENDMENT NO. 1

TO

OFFER LETTER

This Amendment No. 1 to Offer Letter (the "Amendment") is entered into as of April 22, 2018, by and between Menlo Therapeutics Inc., a Delaware corporation (the "Company") and Mary Spellman ("Executive").

RECITALS

WHEREAS, the Company and Executive have entered into that certain Offer Letter, dated as of July 18, 2017, (as amended from time to time, the "Agreement"); and

WHEREAS, the Company and Executive desire to amend the Agreement as provided herein.

NOW, THEREFORE, for good and valuable consideration, receipt of which is hereby acknowledged, the Company and Executive hereby agree to amend the Agreement as follows:

AMENDMENT

1. Amendment. The paragraph titled "At-Will Employment; Severance" is hereby amended and restated to read as follows:

"The Company is an "at-will" employer. Accordingly, either you or the Company may terminate the employment relationship at any time, with or without advance notice, and with or without cause. Upon a termination of your employment by the Company without Cause or by you for Good Reason (together, a "Qualifying Termination"), you will receive a lump-sum payment in cash equal to 9 months' base salary. If you elect to continue coverage under COBRA, subject to your compliance with the provisions of this Agreement, the Company will pay the premiums for such coverage for 9 months following the termination of employment.

Upon a Qualifying Termination during the three (3) months before and twelve (12) month period following a Change in Control (as defined in the 2018 Omnibus Incentive Plan), you will receive a lump-sum payment in cash equal to: 12 months' base salary, up to 12 months' annual bonus (pro-rated monthly for any partial year and measured at "target" achievement), and if you elect to continue coverage under COBRA, subject to your compliance with the provisions of this Agreement, the Company will pay the premiums for such coverage for 12 months following the termination of employment.

Notwithstanding the foregoing, the cash severance benefits described above are conditioned on your executing and letting become irrevocable, within forty-five (45) days of the Qualifying Termination, a general release of claims in favor of the Company, in the form provided by the Company. If you meet this condition, your cash severance will be paid to you within sixty (60) days of the date on which the release becomes irrevocable."

2. Term of Agreement. Except as expressly modified hereby, all terms, conditions and provisions of the Agreement shall continue in full force and effect.

3. Conflicting Terms. In the event of any inconsistency or conflict between the Agreement and this Amendment, the terms, conditions and provisions of this Amendment shall govern and control.

4. Entire Agreement. This Amendment and the Agreement constitute the entire and exclusive agreement between the parties with respect to the subject matter hereof. All previous discussions and agreements with respect to this subject matter are superseded by the Agreement and this Amendment. This Amendment may be executed in counterparts, each of which shall be an original and both of which taken together shall constitute one and the same instrument. This Amendment may be executed and delivered by facsimile and, upon such delivery, the facsimile shall be deemed to have the same effect as if the original signature had been delivered to the other party.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment No. 1 to Offer Letter to be executed by their duly authorized representatives, effective as of the date first written above.

COMPANY:	EXECUTIVE:
Menlo Therapeutics Inc., a Delaware corporation	Mary Spellman
By: /s/ Steve Basta	By: /s/ Mary Spellman
Name: Steve Basta	Mary Spellman
Title: CEO	

Exhibit 31.1

CERTIFICATION

I, Steven Basta, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Menlo 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 company as of, and for, the periods presented in this report;

(4) The company's other certifying officer(s) 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)) for the company 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 company, 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) Evaluated the effectiveness of the company'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

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

(5) The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: November 7, 2018

/s/ Steven Basta
Steven Basta
Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Kristine Ball, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Menlo 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 company as of, and for, the periods presented in this report;

(4) The company's other certifying officer(s) 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)) for the company 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 company, 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) Evaluated the effectiveness of the company'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

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

(5) The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: November 7, 2018

/s/ Kristine Ball
Kristine Ball
Principal Financial Officer

Exhibit 32.1

CERTIFICATION BY THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the Quarterly Report on Form 10-Q of Menlo Therapeutics Inc. (the "Company"), for the quarterly period ended September 30, 2018 as filed with the Securities and Exchange Commission (the "Report"), I, Steven Basta, President and Chief Executive Officer and principal executive officer, hereby certify as of the date hereof, solely for purposes of 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 Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

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

Dated: November 7, 2018

/s/ Steven Basta
Steven Basta
Principal Executive Officer

CERTIFICATION BY THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350

In connection with the Quarterly Report on Form 10-Q of Menlo Therapeutics Inc. (the "Company"), for the quarterly period ended September 30, 2018 as filed with the Securities and Exchange Commission (the "Report"), I, Kristine Ball, Chief Financial Officer and principal financial officer, hereby certify as of the date hereof, solely for purposes of 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 Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

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

Dated: November 7, 2018

/s/ Kristine Ball
Kristine Ball
Principal Financial Officer