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 June 30, 2017

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: 001-36361

Versartis, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**26-4106690**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

4200 Bohannon Drive, Suite 250
Menlo Park, California 94025
(650) 963-8580
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period than the registrant was required to submit and post 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 definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
		Emerging growth company	☒

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

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

As of July 31, 2017, there were 35,578,470 outstanding shares of common stock, par value $0.0001 per share, of Versartis, Inc.

VERSARTIS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED June 30, 2017

PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

VERSARTIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands, except share and per share data)

	June 30, 2017	December 31, 2016
Assets		
Current Assets		
Cash and cash equivalents	$ 143,358	$ 201,153
Prepaid expenses	11,297	4,152
Other current assets	326	—
Total current assets	154,981	205,305
Restricted cash	2,378	—
Property and equipment, net	590	265
Build-to-suit lease asset	9,975	—
Total assets	167,924	205,570
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,550	$ 1,357
Accrued liabilities	22,181	12,899
Income taxes payable	-	247
Upfront payment from collaboration partner (Note 5)	40,000	40,000
Total current liabilities	64,731	54,503
Build-to-suit lease obligation	8,174	$ —
Total liabilities	72,905	54,503
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $0.0001 par value, 50,000,000 shares authorized at June 30, 2017 and December 31, 2016; 35,514,630 and 34,843,885 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	3	3
Additional paid-in capital	450,588	440,667
Accumulated other comprehensive loss	0	(350)
Accumulated deficit	(355,572)	(289,253)
Total stockholders' equity	95,019	151,067
Total liabilities and stockholders' equity	$ 167,924	$ 205,570

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

VERSARTIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Operating expenses				
Research and development	$ 28,618	$ 16,397	$ 50,622	$ 34,589
General and administrative	7,572	5,909	15,228	11,823
Total operating expenses	36,190	22,306	65,850	46,412
Loss from operations	(36,190)	(22,306)	(65,850)	(46,412)
Interest income	242	129	441	234
Other income (expense), net	(521)	59	(782)	(171)
Net loss before provision for income taxes	$ (36,469)	$ (22,118)	$ (66,191)	$ (46,349)
Provision for income taxes	128	—	128	—
Net Loss	$ (36,597)	$ (22,118)	$ (66,319)	$ (46,349)
Net loss per share - basic and diluted	$ (1.04)	$ (0.75)	$ (1.89)	$ (1.57)
Weighted-average common shares used to compute basic and diluted net loss per share	35,316	29,489	35,001	29,455

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

VERSARTIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(unaudited)
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$ (36,597)	$ (22,118)	$ (66,319)	$ (46,349)
Other comprehensive loss:				
Cumulative foreign currency translation adjustment	—	(10)	—	(1)
Unrealized loss on cash flow hedge	—	(258)	—	(205)
Comprehensive loss	$ (36,597)	$ (22,386)	$ (66,319)	$ (46,555)

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

VERSARTIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (66,319)	$ (46,349)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	104	106
Stock-based compensation expense	7,522	5,377
Changes in assets and liabilities		
Prepaid expenses and other assets	(7,122)	(3,636)
Accounts payable	1,194	(940)
Accrued and other liabilities	8,063	547
Income taxes payable	(247)	—
Net cash used in operating activities	(56,805)	(44,895)
Cash flows from investing activities		
Purchase of property and equipment	(1,009)	(90)
Change in restricted cash	(2,380)	—
Net cash used in investing activities	(3,389)	(90)
Cash flows from financing activities		
Proceeds from issuance of common stock in connection with employee benefit plans	2,399	413
Net cash provided by financing activities	2,399	413
Net increase (decrease) in cash and cash equivalents	(57,795)	(44,572)
Cash and cash equivalents at beginning of period	201,153	182,069
Cash and cash equivalents at end of period	$ 143,358	$ 137,497
Supplemental disclosure		
Income taxes paid	$ 375	$ —
Supplemental disclosure of noncash items		
Build-to-suit lease hold improvements	$ 1,219	$ —
Build-to-suit lease transaction	$ 8,174	$ —

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

1. Formation and Business of the Company

Versartis, Inc. (the "Company") was incorporated on December 10, 2008 in the State of Delaware. The Company is an endocrine-focused biopharmaceutical company initially developing long-acting recombinant human growth hormone for the treatment of growth hormone deficiency. The Company is developing drug candidates that it has licensed from Amunix Operating Inc. ("Amunix").

The Company's headquarters and operations are in Menlo Park, California. Since incorporation, the Company has been primarily performing research and development activities, including clinical trials, filing patent applications, obtaining regulatory approvals, hiring personnel, and raising capital to support and expand these activities.

Unaudited Interim Financial Information

In the opinion of the Company, the accompanying unaudited condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of its financial position as of June 30, 2017, its results of operations for the three- and six- months period ended June 30, 2017, and 2016, comprehensive loss for the three- and six- months period ended June 30, 2017 and 2016, and cash flows for the six months ended June 30, 2017, and 2016. The December 31, 2016 condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles in the United States of America, or GAAP. The results for interim periods are not necessarily indicative of the results for the entire year or any other interim period. The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2016 included in the Company's annual report on Form 10-K filed on March 9, 2017 with the U.S. Securities and Exchange Commission ("SEC").

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of the accompanying condensed consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

The accompanying condensed consolidated financial position as of June 30, 2017 and as of December 31, 2016, results of operations and statements of comprehensive loss for the three- and six- month period ended June 30, 2017 and 2016, and cash flows for the six months ended June 30, 2017 and 2016 include the accounts of Versartis, Inc. and its wholly-owned subsidiaries, Versartis Cayman Holdings Company and Versartis GmbH. All intercompany accounts and transactions have been eliminated. The U.S. dollar is the functional currency for all the Company's consolidated operations.

As of June 30, 2017, the Company had cash and cash equivalents balance of $143.4 million consisting of cash and investments in highly liquid U.S. money market funds. The Company believes that its existing cash and cash equivalents will be sufficient to sustain operations for at least the next 12 months from the issuance of these financial statements, based on its existing business plan. While the Company expects additional proceeds if certain clinical and regulatory milestones are met under the Teijin Agreement (see Note 5), if the Company's potential Phase 3 clinical trials are successful, the Company will need to raise additional capital in order to further advance its product candidates towards regulatory approval and potential commercialization. Since inception, the Company has incurred net losses and negative cash flows from operations. At June 30, 2017, the Company had an accumulated deficit of $355.6 million and working capital of $90.3 million. The Company expects to continue to incur losses from costs related to the continuation of research and development and administrative activities for the foreseeable future. Although management has been successful in raising capital in the past, most recently $59.1 million in October and November 2016, there can be no assurance that the Company will be successful or that any needed financing will be available in the future at terms acceptable to the Company.

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.

Concentration of credit risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. All of the Company's cash and cash equivalents are held at multiple financial institutions that management believes are of high credit quality. Such deposits may, at times, exceed federally insured limits.

The Company enters into forward foreign currency contracts that expose it to credit risk to the extent that the counterparties may be unable to meet the terms of the agreement. The Company does, however, seek to mitigate such risks by limiting its counterparties to major financial institutions. In addition, the potential risk of loss with any one counterparty resulting from this type of credit risk is monitored. Management does not expect material losses as a result of defaults by counterparties.

Derivative Financial Instruments

The Company engages in transactions denominated in foreign currencies and, as a result, is exposed to changes in foreign currency exchange rates. To manage the volatility resulting from fluctuating foreign currency exchange rates, the Company enters into option and forward foreign currency exchange contracts.

The Company accounts for its derivative instruments as either assets or liabilities on the balance sheet and measures them at fair value. The Company assesses, both at inception and on an ongoing basis, whether the derivatives that are used in hedging transactions are highly effective in offsetting the changes in cash flows of the hedged items. If the Company determines that a forecasted transaction is no longer probable of occurring, it discontinues hedge accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in other comprehensive income (expense).

Risk and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential drug candidates, uncertainty of market acceptance of the Company's products, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers.

Products developed by the Company require clearances from the U.S. Food and Drug Administration ("FDA"), the Pharmaceuticals Medicines and Devices Agency ("PMDA"), or other international regulatory agencies prior to commercial sales. There can be no assurance that the products will receive the necessary clearances. If the Company was denied clearance, clearance was delayed or the Company was unable to maintain clearance, it could have a materially adverse impact on the Company.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to launch and commercialize any product candidates for which it receives regulatory approval. Even though the Company expects additional proceeds if certain clinical and regulatory milestones are met under the Teijin Agreement, there can be no assurance that such additional financing will be available at all, or at terms acceptable to the Company.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. At June 30, 2017 and December 31, 2016, the Company's cash and cash equivalents were held in multiple institutions in the United States and Europe and included deposits in money market funds which were unrestricted as to withdrawal or use.

Property and Equipment, Net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized.

Build-to-Suit Lease

In the Company's recent lease arrangement (as described in Note 6), the Company is involved in the construction of the building. To the extent the Company is involved with the structural improvements of the construction project or takes construction risk prior to the commencement of a lease, accounting guidance requires the Company to be considered the owner for accounting purposes of these types of projects during the construction period. Therefore, the Company records an asset in property and equipment on the consolidated balance sheet, including capitalized interest costs, for the replacement cost of the Company's leased portion of the pre-existing building. The Company records a corresponding build-to-suit lease obligation on its consolidated balance sheets representing the amounts paid by the lessor.

Once construction is complete, the Company considers the requirements for sale-leaseback accounting treatment, including evaluating whether all risks of ownership have been transferred back to the landlord, as evidenced by a lack of continuing involvement in the leased property. If the arrangement does not qualify for sale-leaseback accounting treatment, the building asset remains on the Company's consolidated balance sheets at its historical cost, and such asset is depreciated over its estimated useful life. The Company bifurcates its lease payments into a portion allocated to the building and a portion allocated to the parcel of land on which the building has been built. The portion of the lease payments allocated to the land is treated for accounting purposes as operating lease payments, and therefore is recorded as rent expense in the consolidated statements of operations. The portion of the lease payments allocated to the building is further bifurcated into a portion allocated to interest expense and a portion allocated to reduce the build-to-suit lease obligation. The interest rate used for the build-to-suit lease obligation represents the Company's estimated incremental borrowing rate at inception of the lease, adjusted to reduce any built in loss. The initial recording of these assets and liabilities is classified as non-cash investing and financing items, respectively, for purposes of the consolidated statements of cash flows.

Impairment of Long-Lived Assets

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by the comparison of the carrying amount to the undiscounted future net cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value (i.e. determined through estimating projected discounted future net cash flows or other acceptable methods of determining fair value) arising from the asset. There have been no such impairments of long-lived assets as of June 30, 2017 or December 31, 2016.

Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level I	Unadjusted quoted prices in active markets for identical assets or liabilities;
Level II	Inputs other than quoted prices included within Level I that are observable, unadjusted 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 related assets or liabilities; and
Level III	Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company's financial instruments consist of Level I and Level II assets. Level I securities are comprised of highly liquid money market funds.

The Company's foreign currency derivative contracts have maturities over a 12-month time horizon and is with a counterparty that has a minimum credit rating of A- or equivalent by Standard & Poor's, Moody's Investors Service, Inc. or Fitch, Inc.

Preclinical and Clinical Trial Accruals

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations ("CROs") that conduct and manage clinical trials on the Company's behalf.

The Company estimates preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical 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 patient enrollment and activity 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.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, laboratory supplies, consulting costs, external research and development expenses and allocated overhead, including rent, equipment depreciation, and utilities. Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are expensed to research and development costs when incurred.

Income Taxes

The Company accounts for income taxes under the asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Stock-Based Compensation

For stock options granted to employees, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding a number of complex and subjective variables.

Stock-based compensation expense related to stock options granted to nonemployees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned. The awards generally vest over the time period the Company expects to receive services from the nonemployee.

Stock-based compensation expense, net of estimated forfeitures, is reflected in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Operating Expenses				
Research and development	$ 1,501	$ 1,020	$ 2,982	$ 1,604
General and administrative	2,157	1,995	4,540	3,773
Total	$ 3,658	$ 3,015	$ 7,522	$ 5,377

Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. Specifically, the Company includes cumulative foreign currency translation adjustments and net unrealized gains and losses on effective cash flow hedges.

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, stock options, restricted stock units and shares issued under our Employee Stock Purchase Plan are considered to be potentially dilutive securities. Because the Company has reported a net loss for all of the periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective is not expected to have a material impact on the Company's financial position or results of operations upon adoption.

In May 2017, the FASB issued, ASU-2017-09, Compensation—Stock Compensation (Topic 718). This guidance clarifies when changes to the terms and conditions of share-based awards must be accounted for as modifications. The guidance does not change the accounting treatment for modifications. The guidance, which will become effective on a prospective basis on January 1, 2018, is not expected to have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued, ASU-2017-01, Business Combinations (Topic 805)- Definition of a Business. This guidance clarifies changes to the definition of a business for accounting purposes. Under the new guidance, an entity first determines whether substantially all of the fair value of a set of assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this threshold is met, the set of assets is not deemed to be a business. If the threshold is not met, the entity then evaluates whether the set of assets meets the requirement to be deemed a business, which at a minimum, requires there to be an input and a substantive process that together significantly contribute to the ability to create outputs. The guidance will become effective on a prospective basis for the Company on January 1, 2018 and is not expected to have a material impact on the Company's consolidated financial statements.

In November 2016, the FASB issued, ASU-2016-18, Statement of Cash Flows (Topic 230)- Restricted Cash. This guidance requires that a statement of cash flows present the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total cash amounts shown on the statement of cash flows. The guidance will become effective on a retrospective basis for the Company on January 1, 2018 and is not expected to have a material impact on the Company's consolidated financial statements.

In August 2016, the FASB issued, ASU 2016-15, Statement of Cash Flows (Topic 230). This ASU simplifies elements of cash flow classification. The guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. The new guidance requires cash payments for debt prepayment or debt extinguishment costs to be classified as cash outflows for financing activities. It also requires cash payments made soon after an acquisition's consummation date (approximately three months or less) to be classified as cash outflows for investing activities. Payments made thereafter should be classified as cash outflows for financing activities up to the amount of the original contingent consideration liability. Payments made in excess of the amount of the original contingent consideration liability should be classified as cash outflows for operating activities. The Company has adopted ASU 2016-15 as of January 1, 2017 and there is no material impact to the 2017 condensed consolidated financial statements.

In March 2016, the FASB issued Accounting Standards Update ASU-2016-09, Compensation – Stock Compensation (Topic 718). This guidance simplified certain aspects of the accounting for share-based payment transactions, including income taxes, classification of awards and classification in the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. The Company will adopt ASU 2016-09 in the first quarter of 2017.

The Company has adopted ASU 2016-09 as of January 1, 2017 and there is no material impact to the 2017 condensed consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU is a comprehensive new leases standard that amends various aspects of existing guidance for leases and requires additional disclosures about leasing arrangements. The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements.

The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous lease guidance. The ASU is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years, and earlier adoption is permitted. In the financial statements in which the ASU is first applied, leases shall be measured and recognized at the beginning of the earliest comparative period presented with an adjustment to equity. The Company is currently evaluating the impact of the adoption of this guidance on its consolidated financial condition, results of operations and cash flows.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes,* which requires all deferred income tax assets and liabilities to be classified as noncurrent on the balance sheet. The new standard is effective for annual reporting periods beginning after December 15, 2016 with early adoption permitted. The Company has adopted ASU 2015-17 as of January 1, 2017 and there is no material impact to the 2017 condensed consolidated financial statements.

In May 2014, the FASB issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB has subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards are effective for interim and annual periods beginning on January 1, 2018, and may be adopted earlier, but not before January 1, 2017. The revenue standards are required to be adopted by taking either a full retrospective approach or a modified retrospective approach. The Company is currently evaluating the impact that the revenue standards will have on the Company's consolidated financial statements and determining the transition method that it will apply.

3. Balance Sheet Components

Prepaid expenses (in thousands)

	June 30, 2017	December 31, 2016
Preclinical and clinical (1)	$ 9,924	$ 3,474
Other	1,373	678
Total	$ 11,297	$ 4,152

(1) These prepayments consist primarily of advances to the Company's contract manufacturers and contract research organizations

Accrued Liabilities (in thousands)

	June 30, 2017	December 31, 2016
Payroll and related	$ 3,608	$ 3,818
Preclinical and clinical	16,789	8,803
Professional services	334	114
Other	1,450	164
Total	$ 22,181	$ 12,899

4. Fair Value Measurements

The Company's financial instruments consist principally of cash and cash equivalents, prepaid expenses, foreign currency exchange contracts, accounts payable and accrued liabilities. The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Fair Value Measurements at June 30, 2017 (unaudited)			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 105,836	$ 105,836	$ —	$ —
	$ 105,836	$ 105,836	$ —	$ —

	Fair Value Measurements at December 31, 2016			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 85,911	$ 85,911	$ —	$ —
	$ 85,911	$ 85,911	$ —	$ —

5. Teijin Agreement

In August 2016, the Company, entered into an Exclusive License and Supply Agreement (the "Agreement") with Teijin Limited, or Teijin, a pharmaceutical company based in Japan, pursuant to which the Company granted to Teijin an exclusive license to develop, use, sell, offer for sale, import, and otherwise commercialize, in Japan, any pharmaceutical product incorporating somavaratan (VRS-317), while Versartis retains exclusive rights to somavaratan in the rest of the world. In exchange for such rights, the Company received an upfront payment of $40.0 million from Teijin, as well as the potential to receive a development milestone of $35.0 million, regulatory milestones of up to $55.0 million, and sales milestones of up to $35.0 million, in addition to sales based payments.

Under the Agreement, the development and commercialization of somavaratan products in Japan will be overseen by a joint steering committee composed of representatives of Teijin and the Company. Versartis will be responsible for completing (at the Company's expense) all ongoing clinical studies, including the current pediatric Growth Hormone Deficiency (GHD) Phase 2/3 trial, and its related long-term safety study, and the Company will also be responsible for a portion of the costs associated with any additional trials, if they are required by the Japanese authorities for approval of the Marketing Authorization Application, or MAA, in Japan in the pediatric indication, up to a cap on our share of such costs of $5.0 million. Following the MAA submission in Japan, Teijin will be responsible for conducting any additional Japanese studies for the pediatric or any other indications, at its own expense.

The Company is required, under the Agreement, to supply Teijin with its clinical and commercial requirements for product for Japan. In exchange for delivering finished product for commercial use, the Company will receive a combination of a running royalty and transfer pricing based upon net sales of the product in Japan, in a percentage ranging from the high-20s to mid-30s.

The Agreement continues until the earlier of (i) twelve years after the first commercial sale of a licensed product in Japan, or (ii) the expiration of certain Versartis patents, unless terminated earlier by mutual agreement of the parties. The initial term of the Agreement is subject to automatic extension for three three-year terms, unless otherwise mutually agreed. The Agreement may be earlier terminated by either party for the other party's uncured material breach or insolvency. In addition, Teijin may terminate the Agreement without cause upon six months' advance notice prior to the sale of a licensed product, and upon twelve months' notice thereafter.

The Company has recorded the $40 million upfront payment received from Teijin as a component of other current liabilities under the caption "Upfront payment from collaboration partner." The Company concluded that the evidence of arrangement criteria pursuant to SEC Staff Accounting Bulletin No. 104 Revenue Recognition and applicable authoritative guidance has not been met as of June 30, 2017. The Company's analysis of the revenue recognition criteria will be completed upon the establishment and completion of the terms of a Commercial Supply Agreement with Teijin governing the supply of finished product to Teijin, as contemplated in the Agreement.

6. Commitments and Contingencies

Facility Leases

In March 2014, the Company entered into an operating facility lease agreement to lease approximately 12,900 square feet in Menlo Park, California for its new headquarters building for a period of thirty-nine months. The total obligation for the Company under this lease is approximately $0.1 million as of June 30, 2017.

In December 2015, the Company entered into an operating sublease agreement to lease approximately 10,900 square feet of additional office space in Menlo Park for a period of twenty-four months. The sublease date began January 1, 2016 and the total obligation under this sublease for the Company is approximately $0.3 million as of June 30, 2017.

In March 2017, the Company entered into an operating facility lease agreement for approximately 34,500 rentable square feet located in the building located at 1020 Marsh Road, Menlo Park, California and for approximately 17,400 rentable square feet located on the second floor of the building located at 1060 Marsh Road. This will serve as the Company's corporate headquarters.

The delivery of the 1020 Space was April 2017. The anticipated delivery for the 1060 Space is November 2017. The initial term of the Lease is 93 months commencing on the date that is 120 days after the 1020 Space is delivered, with one renewal option for a five-year term. We have the option to terminate the lease with respect to the 1060 Space by so notifying Landlord on or before October 31, 2017, in which event the term of the Lease with respect to the 1020 Space will be reduced to 86 months.

With respect to the 1020 Space, base rent shall be approximately $0.2 million per month, subject to 3% annual increases. With respect to the 1060 Space, if we do not opt out, base rent shall be approximately $0.1 million per month, subject to 3% annual increases. In addition to the base rent, the Company shall pay additional rent for the Company's proportionate share of operating expenses, taxes, utilities and insurance expenses for the complex in which the Premises are located.

As an inducement to enter into the lease, Landlord will provide us with approximately a $1.9 million and a $1.0 million tenant improvement allowance for the 1020 Space and the 1060 Space, respectively. We are providing the Landlord with a letter of credit to secure our obligations under the lease in the initial amount of approximately $2.4 million, reported as restricted cash on the balance sheet, to be increased to $3.6 million if we do not elect to terminate the lease with respect to the 1060 Space, which is subject to reductions in future years if certain financial hurdles are met.

Future minimum lease payments under all of our noncancelable operating and facility leases, including the 1020 lease which has not yet commenced, as of June 30, 2017, were as follows (in thousands):

Year Ended December 31,		
2017	$	1,118
2018		3,550
2019		4,103
2020		4,214
2021		4,328
Thereafter		15,307
Total	$	32,620

Build-to-Suit

In March 2017, the Company entered into an operating facility lease agreement, as described above, to lease office space located in Menlo Park, California in a building to be constructed by the landlord. The company expects to occupy the 1020 Space and 1060 Space by August 2017 and February 2018, respectively. The lease has a term of 93 months from the commencement date as defined in the lease agreement with the Company's option to extend the term of the lease for an additional five years. The Company is obligated to make lease payments totaling approximately $32.2 million over the initial term of the lease. In connection with this lease, the landlord is providing a tenant improvement allowance of approximately $1.9 million and $1.0 million for the 1020 Space and the 1060 Space, respectively, for costs associated with the design, development and construction of the Company's improvements. The Company is obligated to fund all costs incurred in excess of the tenant improvement allowance.

Under the terms of the lease agreement, the Company has indemnified the landlord during the construction period. Accordingly, for accounting purposes, the Company has concluded that they are deemed the owner of the building during the construction period and the Company capitalized approximately $10.0 million within property and equipment and recognized an $8.2 million

corresponding build-to-suit obligation in non-current liabilities in the condensed consolidated balance sheet as of June 30, 2017. Of the $10.0 million, approximately $1.2 million has been recorded as a build-to-suit asset and related accrued liability for work performed but net yet paid as of June 30, 2017.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. 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.

As of June 30, 2017 the Company is contingently committed to make development and sales-related milestone payments of up to $30.0 million under certain circumstances, and other payments of $10.0 million, as well as royalties relating to potential future product sales under the License Agreement with Amunix. The amount, timing and likelihood of these payments are unknown as they are dependent on the occurrence of future events that may or may not occur, including approval by the FDA of potential drug candidates.

7. Stockholders' Equity

Equity Incentive Plans

The Company's Board of Directors, or Board, and stockholders previously approved the 2014 Equity Incentive Plan, or the 2014 Plan, which became effective on March 21, 2014. As of June 30, 2017, the total number of shares of common stock available for issuance under the 2014 Plan was approximately 1,120,000. Unless the Board provides otherwise, beginning on January 1, 2015, and continuing until the expiration of the 2014 Plan, the total number of shares of common stock available for issuance under the 2014 Plan will automatically increase annually on January 1 by 4.5% of the total number of issued and outstanding shares of common stock as of December 31 of the immediately preceding year. As of June 30, 2017, approximately 5,788,000 shares of common stock were subject to outstanding awards under the 2014 Plan.

In March 2014, the Board and stockholders approved the 2014 Employee Stock Purchase Plan, or the ESPP, which became effective as of March 5, 2014. The Company initially reserved a total of 150,000 shares of common stock for issuance under the ESPP. Unless the Board provides otherwise, beginning on January 1, 2015, and continuing until the expiration of the ESPP, the total number of shares of common stock available for issuance under the ESPP will automatically increase annually on January 1 by the lesser of (i) 1% of the total number of issued and outstanding shares of common stock as of December 31 of the immediately preceding year, or (ii) 300,000 shares of common stock. As of June 30, 2017, the Company has issued approximately 200,000 shares of common stock under the ESPP.

8. Net loss per share of Common Stock

The following table summarizes the computation of basic and diluted net loss per share of the Company (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$ (36,597)	$ (22,118)	$ (66,319)	$ (46,349)
Weighted-average shares used to compute basic and diluted net loss per share	35,316	29,489	35,001	29,455
Basic and diluted net loss per common share	$ (1.04)	$ (0.75)	$ (1.89)	$ (1.57)

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss per common share by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period, determined using the treasury-stock method and the as-if converted method, for convertible securities, if inclusion of these is dilutive. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per common share for those periods.

The following potentially dilutive securities outstanding at the end of the periods presented have been excluded from the computation of diluted shares outstanding as the effect would be anti-dilutive:

	June 30,	
	2017	2016
Options to purchase common stock	4,898,934	4,403,810
Restricted stock units	889,453	532,835

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

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto for the year ended December 31, 2016, included in our annual report on Form 10-K filed on March 9, 2017 with the U.S. Securities and Exchange Commission (SEC).

Special note regarding forward-looking statements

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "seek," "should," "strategy," "target," "will," "would" and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" included under Part II, Item 1A below. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

Versartis, Inc. (the "Company" "We" "Our") is an endocrine-focused biopharmaceutical company initially developing a novel long-acting form of recombinant human growth hormone, somavaratan (VRS-317), for growth hormone deficiency, or GHD, an orphan disease. A key limitation to current recombinant human growth hormone, or rhGH, products is that they impose the burden of daily injections over multiple years, often resulting in poor adherence, which in turn can lead to suboptimal treatment outcomes in GHD patients. Despite this limitation, global annual sales from currently marketed rhGH products have grown to more than $3.0 billion in 2015. Based on market research, we believe that the market for rhGH products can continue to grow up to $4.0 billion following the launch of long-acting rhGH therapies.

Somavaratan is a fusion protein consisting of rhGH and a proprietary half-life extension technology known as XTEN®. Somavaratan is intended to reduce the burden of daily treatment by requiring significantly fewer dosing events and injections, potentially improving adherence and, therefore, treatment outcomes. Accordingly, we believe somavaratan may take significant market share.

We in-license rights to the XTEN technology from Amunix Operating, Inc., or Amunix, which has granted us an exclusive license under its patents and know-how related to the XTEN technology to develop and commercialize up to four licensed products, including somavaratan. Once we begin commercializing a licensed product, we will owe to Amunix a royalty on net sales of the licensed products until the later of the expiration of all licensed patents or ten years from the first commercial sale in the relevant country. The royalty payable is one percent of net sales for the first two marketed products, but higher single-digit royalties are payable if we market additional products, or if we substitute one marketed product for another. If we elect to substitute one marketed product for another, in addition to royalties, we would also be required to make milestone and other payments totaling up to $40.0 million per marketed product.

In August 2016, we and our wholly-owned subsidiary, Versartis GmbH, entered into an Exclusive License and Supply Agreement with Teijin Limited, or Teijin, pursuant to which we granted to Teijin our exclusive license to develop, use, sell, import or otherwise commercialize in Japan any pharmaceutical product incorporating somavaratan. In exchange for such rights, we received a $40.0 million upfront payment from Teijin, and we may receive a development milestone of $35.0 million, regulatory milestones of up to $55.0 million, sales milestones of up to $35.0 million, and royalty payments.

Pediatric GHD

Our first indication for somavaratan is pediatric GHD, which represents an approximately $1.5 billion existing market opportunity. We have completed the Phase 2a stage of our pediatric GHD clinical trial, have analyzed 36-months of safety and efficacy data from our long-term safety study, also known as our VISTA Study, in pediatric patients and have received feedback from various authorities, including the Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, providing guidance on the design of our Phase 3 clinical trial. In early 2015, we initiated a pediatric GHD Phase 3 registration trial, which we refer to as the VELOCITY trial, and completed enrollment at U.S., Canadian and European sites in August 2016. We also continue to administer somavaratan to patients enrolled in our VISTA Study, which includes rollover patients who have completed the Phase 2a trial and the VELOCITY trial, as well as new treatment-naïve patients. In September 2016, we completed the Phase 2 portion of our pediatric GHD Phase 2/3 registration trial in Japan and have initiated enrollment in the Phase 3 portion of this study following a successful End-of-Phase 2 meeting with Japan's Pharmaceuticals and Medical Devices Agency, or PMDA.

Adult GHD

In August 2015, we initiated an adult GHD Phase 2 trial, which we refer to as the VITAL trial. We completed enrollment in the VITAL trial in April of 2016. We have since initiated a long-term safety study, known as the Protocol 15VR8 trial, where we have transitioned patients completing the VITAL trial to twice-monthly somavaratan dosing.

Other Indications

We may develop somavaratan for additional growth disorders, such as Turner Syndrome, idiopathic short stature, or ISS, and small for gestational age, or SGA, which together accounted for approximately 30% of the global rhGH market in 2015. We have global rights to somavaratan and, if somavaratan is approved, given the highly concentrated prescriber base, we intend to commercialize it with our own specialty sales force in North America, and potentially other geographies.

Financial overview

Summary

We have never generated net income from operations, and, at June 30, 2017, we had an accumulated deficit of $355.6 million, primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments and research and development payments in connection with potential future strategic partnerships, we have not yet generated any revenue. Somavaratan is at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to incur significant and increasing losses from operations for the foreseeable future as we seek to advance somavaratan through its on-going and planned Phase 2 and 3 clinical trials, and there can be no assurance that we will ever generate significant revenue or profits.

Research and development expenses

We recognize both internal and external research and development expenses as incurred. Our external research and development expenses consist primarily of:

- the cost of acquiring and manufacturing clinical trial and other materials, including expenses incurred under agreements with contract manufacturing organizations;
- expenses incurred under agreements with contract research organizations, investigative sites, and consultants that conduct our clinical trials and a substantial portion of our preclinical activities; and
- other costs associated with development activities, including additional studies.

Internal research and development costs consist primarily of salaries and related fringe benefit costs for our employees (such as workers' compensation and health insurance premiums), stock-based compensation charges, travel costs, and allocated overhead expenses.

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we conduct our VELOCITY trial, our ongoing long-term safety studies, our GHD Phase 2/3 registration trial in Japan, and potential Phase 3 Adult GHD trials. As product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials, we expect that our research and development expenses will increase substantially in the future.

General and administrative expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not included in research and development. We anticipate general and administrative expenses will increase in future periods, reflecting an expanding infrastructure, other administrative expenses and increased professional fees associated with being a public reporting company.

Other income (expense), net

Other income (expense), net is primarily comprised of gains and losses on foreign currency transactions related to third-party contracts with foreign-based contract manufacturing organizations as well as gains and losses on foreign currency exchange contracts.

Critical accounting policies, significant judgments and use of estimates

Our management's discussion and analysis of financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, ("U.S. GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in 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 may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed consolidated financial statements and in Note 2 to our audited consolidated financial statements contained in the Annual Report on Form 10-K filed on March 9, 2017 with the Securities Exchange Commission, or the SEC. There have been no significant or material changes in our critical accounting policies during the six months ended June 30, 2017, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Use of Estimates" in the Annual Report on Form 10-K.

Results of operations

Comparison of the Three and Six Months Ended June 30, 2017 and 2016

The following table summarizes our net loss during the periods indicated (in thousands, except percentages):

	Three Months Ended June 30,		Increase/ (Decrease)		Six Months Ended June 30,		Increase/ (Decrease)	
	2017	2016			2017	2016		
Operating expenses:								
Research and development	$ 28,618	$ 16,397	$ 12,221	75%	$ 50,622	$ 34,589	$ 16,033	46%
General and administrative	7,572	5,909	1,663	28%	15,228	11,823	3,405	29%
Loss from operations	(36,190)	(22,306)	13,884	62%	(65,850)	(46,412)	19,438	42%
Interest income	242	129	113	88%	441	234	207	87%
Other income (expense), net	(521)	59	580	984%	(782)	(171)	611	358%
Net loss before provision for income taxes	(36,469)	(22,118)	14,351	65%	(66,191)	(46,349)	19,842	43%
Provision for income taxes	128	-	128	NM	128	-	128	NM
Net loss	$ (36,597)	$ (22,118)	$ 14,479	65%	$ (66,319)	$ (46,349)	$ 19,970	43%

Research and development expense

Research and development expense increased $12.2 million, or 75%, to $28.6 million for the three months ended June 30, 2017 from $16.4 million for the same period in 2016. For the six months ended June 30, 2017 research and development expense increased $16.0 million, or 46%, to $50.6 million from $34.5 million for the same period in 2016. The increase in research and development expense was primarily due to related clinical and manufacturing costs to support our ongoing global VELOCITY pediatric trial and Phase 2/3 trial of somavaratan in pediatric patients in Japan. For the three and six months ended June 31, 2017 and 2016, substantially all of our research and development expense related to our somavaratan drug development activity.

General and administrative expense

General and administrative expense increased $1.7 million, or 28%, to $7.6 million for the three months ended June 30, 2017 from $5.9 million for the same period in 2016. For the six months ended June 30, 2017, general and administrative expense increased $3.4 million, or 29%, to $15.2 million from $11.8 million for the same period in 2016. The increase in G&A expenses was primarily due to additional payroll, consulting, and professional services expenses as we continue to expand our infrastructure to support our growth.

Other income (expense), net

Other expense increased $0.6 million to $0.8 million of other expense for the six months ended June 30, 2017 from other expense of $0.2 million for the same period in 2016. This increase was primarily due to losses on our foreign currency exchange contracts and foreign currency transactions.

Provision for Income taxes

The income tax provision increased to $0.1 million from zero for the three and six months ended June 30, 2017. This increase to our alternative minimum tax primarily reflects the impact of our global business footprint.

Liquidity and capital resources

Since our inception and through June 30, 2017, we have financed our operations through private placements of our equity securities, debt financing and our initial public offering in 2014 and, more recently, additional common stock offerings in January 2015 and October and November of 2016, as well as a $40.0 million upfront payment received from our strategic license agreement with Teijin. At June 30, 2017, we had cash and cash equivalents of $143.4 million, a majority of which is invested in money market funds at several highly rated financial institutions. At June 30, 2017, we had a substantial increase in prepaid expenses, primarily due to our contract manufacturer, Boehringer Ingelheim ("BI") to support our drug substance and drug product for our development programs.

We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of somavaratan and any additional product candidates. Specifically, we have incurred substantial expenses in connection with our VELOCITY trial and we expect to continue to incur substantial expenses in connection with our long-term safety studies and additional Phase 2 and 3 clinical trials that we have initiated or plan to conduct.

While we expect additional proceeds if certain clinical and regulatory milestones are met under the Teijin Agreement, if our ongoing Phase 2 and Phase 3 clinical trials for somavaratan are successful, we will continue to require additional financing to further develop our product candidates and fund operations for the foreseeable future and we will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Although management has been successful in raising capital in the past, most recently $59.1 million in October and November 2016, there can be no assurance that we will be successful or that any needed financing will be available in the future at terms acceptable to the us. 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 in addition to what we may receive from Teijin, the requirements of which will depend on many factors, including:

- the rate of progress and cost of our clinical studies;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the cost of preparing to manufacture somavaratan on a larger scale;
- the costs of commercialization activities if somavaratan or any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our 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.

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 technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

Cash flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Six Months Ended June 30,	
	2017	2016
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (56,805)	$ (44,895)
Investing activities	(3,389)	(90)
Financing Activities	2,399	413
Net increase (decrease) in cash and cash equivalents	$ (57,795)	$ (44,572)

Cash used in operating activities

Net cash used in operating activities was $56.8 million and $44.9 million in the six months ended June 30, 2017 and 2016, respectively, which was primarily due to the use of funds in our operations related to the development of our product candidates. Cash used in operating activities in 2017 increased compared to 2016 due to the substantial increase in prepaid expenses and a higher net loss from operations as we continued to increase our research and development expenditures to develop somavaratan related to our manufacturing and clinical costs and expand our general and administrative functions to support continued growth.

Cash used in investing activities

Cash used in investing activities was $3.4 million and $0.1 million in the six months ended June 30, 2017 and 2016, respectively, which was primarily due to a letter of credit and construction costs associated with our new facility in Menlo Park, California, for which we commenced a new lease in March 2017.

Cash provided by financing activities

Net cash provided by financing activities was $2.4 million and $0.4 million in the six months ended June 30, 2017 and 2016, respectively. Cash provided by financing activities for 2017 consisted of proceeds from issuance of common stock in connection with employee benefit plans.

As of June 30, 2017, we had cash and cash equivalents of approximately $143.4 million. We believe that our existing cash and cash equivalents will be sufficient to sustain operations for at least the next 12 months from the issuance of these financial statements, based on our existing business plan. If our current Phase 3 clinical trials are successful, we will need to raise additional capital in order to further advance our product candidates towards regulatory approval and potential commercialization.

Contractual obligations and commitments

During the six months ended June 30, 2017, there were no material changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in the Annual Report on Form 10-K for the year ended December 31, 2016, except for a new operating lease agreement entered in March 2017 with Bohannon Associates described below:

Bohannon Associates

In March 2017, we entered into an operating facility lease agreement for approximately 34,500 rentable square feet located in the building located at 1020 Marsh Road, Menlo Park, California and for approximately 17,400 rentable square feet located on the second floor of the building located at 1060 Marsh Road. This will serve as the Company's corporate headquarters.

The delivery of the 1020 Space was in April 2017. The anticipated delivery for the 1060 Space is November 2017. The initial term of the Lease is 93 months commencing on the date that is 120 days after the 1020 Space is delivered, with one renewal option for a five-year term. We have the option to terminate the lease with respect to the 1060 Space by so notifying Landlord on or before October 31, 2017, in which event the term of the Lease with respect to the 1020 Space will be reduced to 86 months.

With respect to the 1020 Space, base rent shall be approximately $0.2 million per month, subject to 3% annual increases. With respect to the 1060 Space, base rent shall be approximately $0.1 million per month, subject to 3% annual increases. In addition to the base rent, the Company shall pay additional rent for the Company's proportionate share of operating expenses, taxes, utilities and insurance expenses for the complex in which the Premises are located.

Off-balance sheet arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and qualitative disclosures about market risk

Interest Rate and Market Risk

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our cash and cash equivalents without assuming significant risk. To achieve our objectives, we invest our cash and cash equivalents in money market funds. As of June 30, 2017, we had cash and cash equivalents of $143.4 million consisting of cash and investments in highly liquid U.S. money market funds. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are substantially all short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

Foreign Currency Market Risk

Our relationships with vendors in foreign countries expose us to market risk associated with foreign currency exchange rate fluctuations between the U.S. dollar and various foreign currencies, the most significant of which is the Euro. In order to manage this risk, the Company hedges a portion of its foreign currency exposures related to certain forecasted operating expenses using foreign currency exchange forward or option contracts. In general, the market risk related to these contracts is offset by corresponding gains and losses on the hedged transactions. Our foreign exchange forward contracts expose us to credit risk to the extent that the counterparties may be unable to meet the terms of the agreement. We do, however, seek to mitigate such risks by limiting our counterparties to major financial institutions. In addition, the potential risk of loss with any one counterparty resulting from this type of credit risk is monitored. Management does not expect material losses as a result of defaults by counterparties.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

An evaluation as of June 30, 2017 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our "disclosure controls and procedures." Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the "Exchange Act," defines "disclosure controls and procedures" as controls and other procedures of a company that are designed to ensure that the 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, and that such information is accumulated and communicated to the company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at June 30, 2017.

Changes in Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2017, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. As set forth above, our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II: OTHER INFORMATION

Item 1. Legal proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the following risks, together with all the other information in this Form 10-Q, including our condensed consolidated financial statements and notes thereto. If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment.

Risks related to the development and commercialization of our product candidate

Our success depends heavily on the successful development, regulatory approval and commercialization of our only product candidate, somavaratan.

We do not have any products that have gained regulatory approval. Our only clinical-stage product candidate is somavaratan, a novel, long-acting recombinant human growth hormone. We have completed the Phase 2a stage of a Phase 1b/2a clinical trial in children with growth hormone deficiency, or GHD, and initiated our North American and European Phase 3 pediatric GHD clinical trial, the VELOCITY trial, of somavaratan in early 2015. We have since completed enrollment of the VELOCITY trial as of August 2016. In September 2016, we initiated the Phase 3 portion of our Phase 2/3 pediatric GHD clinical trial of somavaratan in Japan. We initiated a Phase 2 adult GHD clinical trial, the VITAL trial, of somavaratan in September 2015, and completed enrollment in April 2016. As a result, our near-term prospects, including our ability to finance our operations and generate revenue, are substantially dependent on our ability to obtain regulatory approval for and, if approved, to successfully commercialize somavaratan in a timely manner.

We cannot commercialize somavaratan or any future product candidates in the United States without first obtaining regulatory approval for the product from the U.S. Food and Drug Administration, or FDA, nor can we commercialize somavaratan or any future product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA review process typically takes years to complete and approval is never guaranteed. Before obtaining regulatory approvals for the commercial sale of somavaratan for a target pediatric GHD indication or our future product candidates, we generally must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical studies that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. We are pursuing the same regulatory pathway for somavaratan followed by most of the approved rhGH products for pediatric GHD patients: a dose-finding study and a Phase 3 non-inferiority registration trial with a primary endpoint of mean Year 1 height velocity. In addition, while the available growth data from published studies of approved rhGH therapy products suggest that three, six and twelve month mean height velocities are well correlated within the same clinical trial, it is possible that somavaratan, due to its unique properties, will produce different results. If mean Year 1 height velocities that we observed for somavaratan in ongoing long-term safety studies do not correlate to mean Year 1 height velocities that we ultimately observe in any Phase 3 clinical trial that we are conducting, somavaratan may not achieve the required primary endpoint in the Phase 3 clinical trial, and somavaratan may not receive regulatory approval.

Moreover, obtaining regulatory approval for marketing of somavaratan in one country does not ensure we will be able to obtain regulatory approval in other countries, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Even if somavaratan or any of our future product candidates were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for somavaratan in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue to fund our operations. Also, any regulatory approval of somavaratan or our future product candidates, once obtained, may be withdrawn. Furthermore, even if we obtain regulatory approval for somavaratan, the commercial success of somavaratan will depend on a number of factors, including the following:

- development of our own commercial organization or establishment of a commercial collaboration with a commercial infrastructure;
- establishment of commercially viable pricing and obtaining approval for adequate reimbursement from third-party and government payors;

- the ability of our third-party manufacturers to manufacture quantities of somavaratan using commercially viable processes at a scale sufficient to meet anticipated demand and reduce our cost of manufacturing, and that are compliant with current Good Manufacturing Practices, or cGMP, regulations;
- our success in educating physicians and patients about the benefits, administration and use of somavaratan;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the effectiveness of our own or our potential strategic collaborators' marketing, sales and distribution strategy and operations;
- acceptance of somavaratan as safe and effective by patients, caregivers and the medical community;
- a continued acceptable safety profile of somavaratan following approval; and
- continued compliance with our obligations in our intellectual property licenses with third parties upon favorable terms.

Many of these factors are beyond our control. If we or our commercialization collaborators are unable to successfully commercialize somavaratan, we may not be able to earn sufficient revenues to continue our business.

Somavaratan is a new molecular entity, and although it contains the same rhGH composition used in currently approved rhGH products, it has been genetically modified to extend its half-life, creating uncertainty about its long-term safety profile.

Somavaratan utilizes the same rhGH amino acid sequence as in currently approved rhGH products, but combined with sequences of hydrophilic amino acids genetically fused to the rhGH protein to extend its half-life. This proprietary in-licensed half-life extension technology, XTEN, has been used in somavaratan to potentially enable less frequent administration of rhGH. We have limited clinical data on product candidates utilizing XTEN technology indicating whether they are safe or effective for long-term treatment in humans. The long term safety and efficacy of the XTEN technology and the extended half-life and exposure profile of somavaratan compared to currently approved rhGH products is unknown, and it is possible it may increase the risk of unforeseen reactions to somavaratan following extended treatment relative to other currently approved rhGH products. Continuously elevated levels of rhGH and insulin-like growth factor-I, or IGF-I, together can lead to acromegaly, a rare disease that occurs when the body produces excess growth hormone, leading to an increase in the size of bones and organs and which can result in disfigurement and other complications, with an associated increased cancer risk. It is unknown whether long-term repeated administration of somavaratan could result in an increased immune response to rhGH, leading to a loss of efficacy or potential safety issues. If extended treatment with somavaratan in our ongoing or future clinical trials results in any concerns about its safety or efficacy, we may be unable to successfully develop or commercialize somavaratan.

Because the results of preclinical testing and earlier clinical trials and the results to date in our VISTA long-term safety study are not necessarily predictive of future results, somavaratan may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical testing and early clinical trials and the results to date in our VISTA study do not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. Despite the results to date in our ongoing VISTA study of somavaratan in GHD children and the results reported in earlier trials, we do not know whether the clinical trials we are conducting, or may conduct, will demonstrate adequate efficacy and safety to result in regulatory approval to market somavaratan. Even if we believe that we have adequate data to support an application for regulatory approval to market our product candidates, the FDA, European Medicines Agency, or EMA, or other applicable foreign regulatory authorities may not agree and may require that we conduct additional clinical trials. If our Phase 3 clinical trial of somavaratan in GHD children or other later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for somavaratan may be adversely impacted.

There can be no assurance that somavaratan will not exhibit new or increased safety risks in the Phase 3 clinical trial as compared to the Phase 1b/2a clinical trial or ongoing VISTA study. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many other companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their products.

In addition, we have not yet confirmed that the selected Phase 3 dose of somavaratan administered for 12 months will provide adequate efficacy to support registration. There can be no guarantee that the dose studied in the Phase 3 clinical trial will be efficacious or, if it is, whether it will be the optimal dose. There cannot be any guarantee that any of these studies will be successful in determining a dose or dose regimen of somavaratan suitable for marketing approval.

As an organization, we have never completed a Phase 3 clinical trial or submitted a BLA before, and may be unsuccessful in doing so for somavaratan.

The conduct of our Phase 3 clinical trials and other supportive trials of somavaratan and the submission of a successful Biologics License Application, or BLA, is a complicated process. As an organization, we have never completed a Phase 3 clinical trial, have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted a BLA before. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA submission and approval of somavaratan. Failure to complete, or delays in our clinical trials would prevent us from or delay us in commercializing somavaratan.

Long-acting rhGH products and product candidates no longer in development or marketed have failed to generate commercial success or obtain regulatory approval, and we cannot predict whether somavaratan will achieve success where others have failed.

Many attempts have been made to develop sustained release formulations of rhGH. For example, Nutropin Depot, a long-acting form of rhGH developed by Genentech that uses Alkermes' ProLease® injectable extended-release drug delivery system, was approved by the FDA in 1999 and withdrawn from the market in 2004 by Genentech and Alkermes due to the significant resources required to continue manufacturing and commercializing the product. Additional attempts at sustained release formulations have not yet led to globally marketed products, due to manufacturing, regulatory, efficacy and/or safety reasons. Even if we obtain all requisite regulatory approvals, no assurance can be given that somavaratan will achieve commercial success or market adoption.

Delays in the enrollment of patients in any of our clinical studies could increase our development costs and delay completion of the study.

We may not be able to initiate or continue clinical studies for somavaratan or any future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these studies as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical studies, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our studies may be delayed or our studies could become too expensive to complete.

We will need to enroll patients at forecasted rates at both new and existing clinical sites. Our forecasts regarding the rates of clinical site activation and patient enrollment at those sites are based on a number of assumptions, including assumptions based on past experience. However, there can be no assurance that those forecasts will be accurate or that we will not face delays in our clinical trials. Enrollment in our clinical trials is dependent on obtaining clearance from regulatory authorities in each country in which they will be conducted. To date, authorities in several countries have declined clinical trial applications or requested additional data or information prior to authorizing such applications in those countries. If we are unable to provide sufficient responses to the regulatory authorities during the conduct of the studies, they may be delayed.

There may be concurrent competing GHD clinical trials that will inhibit or slow our enrollment in any Phase 3 clinical trial or other trials we conduct. If we experience delays in enrollment, our ability to complete any clinical trial could be impaired and the costs of conducting the trial could increase, either of which could have a material adverse effect on our business.

If clinical studies of somavaratan and any future product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce results that are acceptable to such agencies, we may incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of somavaratan or our future product candidates.

Before obtaining regulatory approval for the sale of any product candidate, we must conduct extensive clinical studies to demonstrate the safety and efficacy of our product candidates in humans. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of our clinical studies could occur at any stage of testing.

We may experience numerous unforeseen events during, or as a result of, clinical studies that could delay or prevent our ability to receive regulatory approval or commercialize somavaratan or any future product candidates, including the following:

- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate or patients may drop out of these clinical studies at a higher rate than we anticipate;
- the cost of clinical studies or the manufacturing of our product candidates may be greater than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies of our product candidates for various reasons, including a finding that our product candidates have unanticipated serious side effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;
- regulators may not approve our proposed clinical development plans;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical studies of our product candidates may be insufficient or inadequate.

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed or used.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any clinical studies will begin as planned, will need to be restructured or will be completed on schedule, or at all. For example, in February 2014, the FDA notified us that it would require additional information before allowing us to use a newly manufactured lot of somavaratan produced by our new manufacturer intended for our ongoing VISTA Study, and the FDA subsequently issued a partial clinical hold related to the use of any material produced by this new manufacturer. The FDA ultimately lifted the partial clinical hold in June 2014. And then in early 2015, following initiation of the VELOCITY trial, the FDA requested additional bioanalytical data and placed our Phase 3 clinical trial on partial clinical hold. We provided the requested information to the agency and this second partial clinical hold was lifted in June 2015. There can be no assurance, however, that we will not be subject to similar FDA actions in the future, or that such actions will not cause delays in our clinical studies.

Significant clinical study delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to commercialize our product candidates and harm our business and results of operations.

Somavaratan or our future product candidates may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any marketing approval.

Our product candidate, somavaratan, has not completed clinical development. The risk of failure of clinical development is high. It is impossible to predict when or if somavaratan or any future product candidates will prove safe enough to receive regulatory approval. Undesirable side effects caused by somavaratan or any future product candidates 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 foreign regulatory authorities.

Somavaratan is in active development for pediatric GHD and adult GHD, and safety data have been reported from seven clinical studies of somavaratan in GHD patients. In these studies, adverse events (AEs) associated with somavaratan administration have generally been mild or moderate and transient, have been observed most frequently at or shortly following administration of the first dose, and have been consistent with those typically reported and observed in children starting daily rhGH. Suspected serious adverse drug reactions have been rare. In the ongoing Phase 2 extension study in Japan, one potentially related serious AE (seizure) was reported in a child with both a medical history and clinical findings consistent with a preexisting condition. Reference safety information for somavaratan has been established based on frequency of reported events and clinical judgment. Events considered expected for the purposes of regulatory reporting include injection site pain and headache in adults and children with GHD. However,

we cannot provide assurance that serious adverse events or clinically meaningful adverse events will not occur at a higher rate in current or future clinical trials or that side effects in general will not prompt the discontinued development of somavaratan or any future product candidates.

In addition, the administration of therapeutic proteins including recombinant hGH occasionally causes an immune response, resulting in the creation of antibodies against the protein. The antibodies may be transient or persistent and can have no effect or can neutralize the activity of the protein or accelerate its clearance. Antibodies, including the rare occurrence of neutralizing antibodies, have been observed in the somavaratan clinical trials and while they had no effect on occurrence of adverse events, their overall clinical relevance must be assessed in our Phase 3 clinical trials. Due to potential safety, efficacy, immunogenicity, or toxicity issues that we may experience in our clinical trials in the future, we may not receive approval to market somavaratan or any future product candidates, which could prevent us from ever generating revenue or achieving profitability. Results of our trials could reveal an unacceptably high severity or prevalence of side effects or antibodies. In such an event, our trials could be suspended or terminated and the FDA or foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. Any drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects.

Additionally, if somavaratan or any of our future product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend the marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of Risk Evaluation Mitigation Strategies, or REMS, or a foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

Even if our clinical trials demonstrate acceptable safety and efficacy of somavaratan for growth in pediatric GHD patients based on a twice-monthly dosing regimen, the FDA or similar regulatory authorities outside the United States may not approve somavaratan for marketing or may approve it with restrictions on the label, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Assuming the success of our clinical trials, we anticipate seeking regulatory approval for somavaratan in the United States, Europe and Canada for treatment of pediatric GHD patients based on a twice-monthly dosing regimen. It is possible that the FDA, the EMA, the PMDA or Health Canada may not consider the results of our clinical trials to be sufficient for approval of somavaratan for this indication. In general, the FDA suggests that sponsors complete two adequate and well-controlled clinical studies to demonstrate effectiveness because a conclusion based on two persuasive studies will be more compelling than a conclusion based on a single study. Even if we achieve favorable results in our Phase 3 clinical trial, and considering that somavaratan is a new molecular entity, the FDA may nonetheless require that we conduct additional clinical studies, possibly using a different clinical study design.

Moreover, even if the FDA or other regulatory authorities approve somavaratan for treatment of pediatric GHD patients based on twice-monthly dosing, the approval may include additional restrictions on the label that could make somavaratan less attractive to physicians and patients compared to other products that may be approved for broader indications, which could limit potential sales of somavaratan.

If we fail to obtain FDA or other regulatory approval of somavaratan or if the approval is narrower than what we seek, it could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Even if somavaratan or any future product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payors and others in the medical community necessary for commercial success.

If somavaratan or any future product candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payors and others in the medical community. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including the following:

- the prevalence and severity of any side effects;
- their efficacy and potential advantages compared to alternative treatments;
- the price we charge for our product candidates;
- the willingness of physicians to change their current treatment practices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support; and
- the availability of third-party coverage or reimbursement.

For example, a number of companies offer therapies for treatment of pediatric GHD patients based on a daily regimen, and physicians, patients or their families may not be willing to change their current treatment practices in favor of somavaratan even if it is able to offer less frequent dosing. If somavaratan or any future product candidates, if approved, do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable on a sustained basis or at all.

Somavaratan has never been manufactured for commercial use, and there are risks associated with scaling up manufacturing and validating the process for production of commercial material. In addition, to successfully commercialize somavaratan, we also intend to design, manufacture, and gain regulatory approval of a delivery device to safely, effectively, and conveniently administer somavaratan in relevant patient types.

Somavaratan has been successfully manufactured for use in clinical studies but there are risks associated with scaling up manufacturing to commercial scale and validating the commercial production process including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. Even if we could otherwise obtain regulatory approval for somavaratan, there is no assurance that our manufacturer will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand.

If our manufacturer is unable to produce sufficient quantities of the approved product for commercialization under our supply agreement, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Somavaratan is a biological molecule, or biologic, rather than a small molecule chemical compound, and as a result we face special uncertainties and risks associated with scaling up manufacturing. The manufacture of biologics involves complex processes, including developing cells or cell systems to produce the biologic, growing large quantities of such cells and harvesting and purifying the biologic produced by them. As a result, the cost to manufacture biologics is generally far higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is difficult to reproduce. Somavaratan was previously produced for us by a third-party contract manufacturer using a small-scale process that was too expensive and inefficient to support the dosages necessary for our ongoing and planned clinical trials. In October 2012, we entered into an agreement with Boehringer Ingelheim to develop a more efficient, larger-scale manufacturing process. However, scaling up and improving a biologic manufacturing process is a difficult and uncertain task, and we can give no assurance that we will be successful in developing and implementing this new process. Additionally, if we receive regulatory approval for somavaratan, in order to successfully commercialize somavaratan, we will need to manufacture quantities of somavaratan using commercially viable processes at a scale sufficient to meet anticipated demand. Even if we are able to do so, if the therapeutically effective dosage of somavaratan is higher than we anticipate or the obtainable sales price is lower than we anticipate, we may not be able to successfully commercialize somavaratan.

To optimally commercialize somavaratan, we intend to design, manufacture, and gain regulatory approval of two distinct container closure systems, including the vial configuration used in the pivotal clinical trial and a delivery device to safely, effectively and conveniently administer the drug. In May 2016, we entered into a Manufacture and Supply Agreement with Owen Mumford Limited, under which they will manufacture a proprietary disposable autoinjector device for the administration of somavaratan and

assemble the final combination product. Manufacturing of a precision medical device like the autoinjector is complex and introducing a novel device requires designing, production of prototypes, extensive testing and modification, and production of custom tools and molds. If we and Owen Mumford are unable to develop and validate a suitable manufacturing process for the device, our commercialization efforts could be impaired, which could have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our failure to successfully identify, acquire, develop and commercialize additional products or product candidates could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued clinical testing and potential approval of our most advanced product candidate, somavaratan, a key element of our long-term growth strategy is to acquire, develop and/or market additional products and product candidates. We currently have one other potential product candidate that is in the preclinical study stage, but its development is at a preliminary stage and there can be no certainty that we will choose to advance it. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure.

Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured profitably or achieve market acceptance.

We currently have no sales or distribution personnel and only limited marketing capabilities. If we are unable to develop a sales and marketing and distribution capability on our own or through collaborations or other marketing partners, we will not be successful in commercializing somavaratan or other future products.

We do not have a significant sales or marketing infrastructure and have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. If somavaratan is approved, we intend to commercialize it with our own specialty sales force in North America and potentially other geographies.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We also may not be successful entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and could damage our reputation. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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

The development and commercialization of new therapeutic products is highly competitive. We face competition with respect to somavaratan, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell rhGH therapies to our target patient group. These companies typically have a greater ability to reduce prices for their competing drugs in an effort to gain or retain market share and undermine the value proposition that we might otherwise be able to offer to payors. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

We are developing our lead product candidate, somavaratan, for treatment of pediatric and adult GHD patients based on a twice-monthly dosing regimen. The current standard of care for growth therapies for patients in the United States and around the world is a daily subcutaneous injection of rhGH. There are a variety of currently marketed daily rhGH therapies administered by daily subcutaneous injection and used for the treatment of GHD, principally Norditropin® (Novo Nordisk), Humatrope® (Eli Lilly), Nutropin-AQ® (Roche/Genentech), Genotropin® (Pfizer), Saizen® (Merck Serono), Zomacton™ (Ferring Pharmaceuticals), Omnitrope® (Sandoz GmbH) and Valtropin® (LG Life Science). These rhGH drugs, with the exception of Valtropin®, are well-established therapies and are widely accepted by physicians, patients, caregivers, third-party payors and pharmacy benefit managers, or PBMs, as the standard of care for the treatment of GHD. Physicians, patients, third-party payors and PBMs may not accept the addition of somavaratan to their current treatment regimens for a variety of potential reasons, including concerns about incurring potential additional costs related to somavaratan, the perception that the use of somavaratan will be of limited additional benefit to patients, or limited long-term safety data compared to currently available rhGH treatments.

In addition to the currently approved and marketed daily rhGH therapies, there are a variety of experimental therapies that are in various stages of clinical development by companies both already participating in the rhGH market as well as potential new entrants, principally Aileron Therapeutics, Althea, Ambrx, Ascendis, Bioton S.A., Critical Pharmaceuticals, Dong-A, GeneScience, Genexine, Hanmi, LG Life Science, OPKO Health, Inc. (in collaboration with Pfizer, Inc.) and all of the existing global and regional rhGH franchises.

Many of our competitors, including a number of large pharmaceutical companies that compete directly with us, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

We have and may continue to form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships or those like them may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for somavaratan or any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

If we are able to commercialize somavaratan or any future product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize somavaratan or any future products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to

control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacturing, sales and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take nine to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. Our business could be materially harmed if reimbursement of our approved products, if any, is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

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

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

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold $10.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. 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.

Risks related to our financial condition and need for additional capital

We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial and increasing losses for the foreseeable future. We have only one product candidate and no commercial sales, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We do not have any products approved for sale, and to date we have focused principally on developing our only product candidate, somavaratan. Evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or approved products on the market. We continue to incur significant research and development and general and administrative expenses related to our operations. Investment

in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. We have incurred significant operating losses in each year since our inception and expect to incur substantial and increasing losses for the foreseeable future. As of June 30, 2017, we had an accumulated deficit of $355.6 million.

To date, we have financed our operations primarily through private placements of our convertible preferred stock, the initial public offering of our common stock in March 2014, and public offerings of our common stock in January 2015, October and November of 2016. We have devoted substantially all of our efforts to research and development, including clinical studies, but have not completed development of any product candidate. We anticipate that our expenses will increase substantially as we:

- continue the research and development of our only product candidate, somavaratan, and any future product candidates;
- continue clinical studies of somavaratan, including the Phase 3, Phase 2/3, and Phase 2 clinical trials of somavaratan that we initiated in 2015, which will be our most expensive clinical trials to date;
- seek to discover or in-license additional product candidates;
- seek regulatory approvals for somavaratan and any future product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize somavaratan or other future product candidates if they obtain regulatory approval, including process improvements in order to manufacture somavaratan at commercial scale; and
- enhance operational, financial and information management systems and hire more personnel, including personnel to support development of somavaratan and any future product candidates and, if a product candidate is approved, our commercialization efforts.

To be profitable in the future, we must succeed in developing and eventually commercializing somavaratan as well as other products with significant market potential. This will require us to be successful in a range of activities, including advancing somavaratan and any future product candidates, completing clinical studies of these product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We are only in the preliminary stages of some of these activities. We may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if we are profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product candidates, market our product candidates, if approved, or continue our operations.

We currently have no source of product revenue and may never become profitable.

To date, we have not generated any revenues from commercial product sales, or otherwise. Even if we are able to successfully achieve regulatory approval for somavaratan or any future product candidates, we do not know when any of these products will generate revenue from product sales for us. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability, alone or with current and any future collaborators, to successfully commercialize products, including somavaratan or any product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenue from product sales from somavaratan or any future product candidates also depends on a number of additional factors, including our or any future collaborators' ability to:

- complete development activities, including our ongoing long-term safety studies and Phase 3, Phase 2/3, and Phase 2 clinical trials of somavaratan, successfully and on a timely basis;
- demonstrate the safety and efficacy of somavaratan to the satisfaction of the FDA and obtain regulatory approval for somavaratan and future product candidates, if any, for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- set a commercially viable price for our products;
- establish and maintain supply and manufacturing relationships with reliable third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop a commercial organization capable of sales, marketing and distribution of any products for which we obtain marketing approval in markets where we intend to commercialize independently;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;

- achieve market acceptance of our products, if any;
- establish, maintain and protect our intellectual property rights and avoid third-party patent interference or patent infringement claims; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that somavaratan or any future product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide to or are required by the FDA or foreign regulatory authorities to perform studies or trials in addition to those that we currently anticipate. Even if we are able to complete the development and regulatory process for somavaratan or any future product candidates, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of somavaratan or any future product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or shut down our operations.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any current and potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to somavaratan and any future product candidates, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing somavaratan and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical studies for somavaratan and any future product candidates or competing product candidates;
- changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of somavaratan or any of our future product candidates;
- the level of demand for somavaratan and any future product candidates, should they receive approval, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- competition from existing and potential future drugs that compete with somavaratan or any of our future product candidates;
- our ability to commercialize somavaratan or any future product candidate inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;

- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

We will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates and technologies.

The completion of the development and the potential commercialization of somavaratan and any future product candidates, should they receive approval, will require substantial funds. As of June 30, 2017, we had approximately $143.4 million in cash and cash equivalents, and we received an additional $59.1 million in net proceeds from our public offering in October and November 2016. We believe that our existing cash and cash equivalents, combined with the proceeds of the recent offering, will be sufficient to sustain operations for at least the next 12 months based on our existing business plan. Our future financing requirements will depend on many factors, some of which are beyond our control, including the following:

- the rate of progress and cost of our clinical studies;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the cost of preparing to manufacture somavaratan on a larger scale;
- the costs of commercialization activities if somavaratan or any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
- the emergence of competing technologies or other adverse market developments; and
- the costs of attracting, hiring and retaining qualified personnel.

We do not have any material committed external source of funds or other support for our development efforts. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to somavaratan or potential future product candidates, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies or research and development programs or our commercialization efforts.

Risks related to our reliance on third parties

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

We do not independently conduct clinical studies of our lead product candidate, somavaratan. We rely on third parties, such as contract research organizations, or CROs, clinical data management organizations, medical institutions and clinical investigators, to perform this function. For example, we currently rely on ResearchPoint Global to oversee and manage our ongoing VISTA study and global Phase 3 pediatric trial of somavaratan. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical studies are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also rely on other third parties to store and distribute supplies for our clinical studies. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We rely on third-party contract manufacturing organizations to manufacture and supply somavaratan, including our autoinjector device. If our manufacturers and suppliers fail to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find a new supplier or manufacturer. We may also face delays in the development and commercialization of our product candidates.

We currently have limited experience in, and we do not own facilities for, clinical-scale manufacturing of our product candidates and we currently rely upon third-party contract manufacturing organizations to manufacture and supply drug product for our clinical studies of somavaratan. The manufacture of pharmaceutical and medical device products in compliance with the cGMP and Quality System (QS) regulations and guidance from various regulatory authorities requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP/QS requirements, other federal and state regulatory requirements and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to provide study drugs in our clinical studies would be jeopardized. Any delay or interruption in the supply of clinical study materials could delay the completion of our clinical studies, increase the costs associated with maintaining our clinical study programs and, depending upon the period of delay, require us to commence new studies at significant additional expense or terminate the studies completely.

All manufacturers of our product candidates must comply with cGMP and QS requirements enforced by the FDA, EMA, PMDA and similar authorities through their facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these requirements and with other regulatory authority requirements. Regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical studies, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or impair our reputation.

Our product candidate, somavaratan, is a biologic and therefore requires a complex production process. In October, 2012, we transferred production of somavaratan to Boehringer Ingelheim. In connection with the transfer of production, we made certain changes to the manufacturing process in order to increase its scale and efficiency. We cannot assure that the FDA and the EMA will agree to the changes in the manufacturing process to support commercialization. In addition, current agreements with our manufacturer do not provide for the entire supply of the drug product necessary for full scale commercialization. If we and our manufacturer cannot agree to the terms and conditions necessary for our commercial supply needs, or if our manufacturer terminates the agreement in response to a material breach by us or otherwise becomes unable to fulfill its supply obligations, we would not be able to manufacture somavaratan until a qualified alternative manufacturer is identified, which could also delay the development of, and impair our ability to commercialize, somavaratan.

We expect to seek regulatory approval for somavaratan in the vial configuration as well as a drug/device combination product including somavaratan and an autoinjector. We anticipate availability of one or both configurations at or following the initial regulatory approval. The autoinjector is a new medical device that has not been approved or cleared in any jurisdiction and will be manufactured by Owen Mumford Limited in the United Kingdom. We cannot assure that the autoinjector will be manufactured in compliance with all applicable device QS requirements in a manner acceptable to applicable regulatory authorities. In addition, we are reliant upon Owen Mumford as the sole supplier of the autoinjector and if it is unable to supply the device at the volume required for conduct of our clinical trials and potential commercialization, the availability of somavaratan combination product may be impacted.

The number of third-party manufacturers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. New manufacturers of any product candidate would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product candidate. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us.

Our current and potential future license or collaboration agreements for somavaratan or any other product candidate may place some or all aspects of the development and commercialization of somavaratan or other product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

We have entered into and may in the future enter into additional license or collaboration agreements with third parties for the development or commercialization of somavaratan or future product candidates. In August 2016, we entered into an Exclusive License and Supply Agreement, or the Teijin License, with Teijin Limited, or Teijin, pursuant to which we granted to Teijin an exclusive license to develop, use, sell, offer for sale, import or otherwise commercialize in Japan any pharmaceutical product incorporating somavaratan. Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include pharmaceutical and biotechnology companies such as Teijin. Because such collaborators are independent third parties, they may be subject to different risks than we are and may have significant discretion in, and different criteria for, determining the efforts and resources they will apply related to their agreements with us. We may have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates are subject to numerous risks, which may include the following:

- Collaborators have significant discretion in determining the efforts and resources that they will apply to any such collaborations. For instance, under the Teijin License, while we are responsible for the ongoing Japanese Phase 2/3 clinical trial of somavaratan, Teijin will be responsible for commercialization activities in Japan.
- Collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical study results, changes in their strategic focus, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities.
- Collaborators may assume responsibility for conduct of clinical trials for product candidates in certain geographies and may fail to conduct such trials, may conduct them improperly, or may generate data inconsistent with the data from our clinical trials. For example, Teijin has the right to conduct certain clinical trials of somavaratan in Japan and if such trials generate data that conflicts with the VELOCITY trial or other Versartis-sponsored studies, the approvability or labeling of the product may be impacted in the US, Europe and other jurisdictions outside Japan.

- Collaborators may assume responsibility for seeking or maintaining regulatory approvals, pricing, government reimbursement approval, and public and private formulary placements. Failure to effectively obtain such approvals and clearances will substantially impact the commercial potential for the product candidate. For example, following completion of the Phase 2/3 study of somavaratan in Japan, Teijin will become responsible for Japanese regulatory activities, including submitting the Japanese New Drug Application (JNDA) to the PMDA to obtain initial marketing approval.
- Collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a product candidate, repeat or conduct new clinical studies or require a new formulation of a product candidate for clinical testing.
- Collaborators may be required to conduct duplicate analytical testing of a product candidate or approved product upon importation to a specific jurisdiction. If, for example, Teijin conducts limited release testing of somavaratan for sale in Japan, data generated could be inconsistent with the testing conducted by BI or other third parties upon initial release, which would require investigation and resolution and could impact our ability to continue distribution of released material.
- Collaborators could acquire or independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates.
- A collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution. For example, Teijin is responsible for all sales, marketing and related activities for somavaratan in Japan and if it fails to adequately resource these functions, the product is unlikely to reach expected revenue targets for Japan.
- The actions of a collaborator may create liability for us as the global manufacturer of a product candidate, either directly or through indemnification obligations defined in license, collaboration or other agreements.
- 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 publish or otherwise publicly present or disclose information regarding our product candidates, including laboratory data or the results of preclinical or clinical research.
- Disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.
- Collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

Risks related to the operation of our business

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

We are highly dependent on our chief executive officer and the other principal members of our executive team, substantially all of whom joined our company prior to May 2015, when our current chief executive officer began serving in that role. We recently added under the terms of their employment, our executives may terminate their employment with us at any time. The loss of the services of any of these people or instability in our executive team, which may be more likely due to our recent leadership changes, could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of July 31, 2017, we had 71 employees. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively, which we anticipate being conducted at numerous clinical sites;
- identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience we will require;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- managing additional relationships with various strategic partners, suppliers and other third parties;
- improving our managerial, development, operational and finance reporting systems and procedures; and
- expanding our facilities.

Our failure to accomplish any of these tasks could prevent us from successfully growing our company. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various 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 of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) December 31, 2019, (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, among other things, that the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (3) the date on which we have issued more than $1.07 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act 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, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our corporate headquarters are located in California and certain clinical sites for our product candidate, operations of our existing and future partners are or will be located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant partners, suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural or manmade disaster.

If we obtain approval to commercialize somavaratan outside the United States, we will be subject to additional risks.

If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- 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 revenue, 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; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

The United Kingdom's impending departure from the European Union could adversely affect our business.

The United Kingdom held a referendum on June 23, 2016 in which a majority of voters voted to exit the European Union ("Brexit"). Negotiations are expected to commence to determine the future terms of the United Kingdom's relationship with the European Union, including, among other things, the terms of trade between the United Kingdom and the European Union. The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to European Union markets either during a transitional period or more permanently. Brexit could adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets, including volatility in the value of the sterling and euro. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws to replace or replicate, including laws that could impact our ability to obtain approval of our products or sell our products in the United Kingdom. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, results of operations, financial condition and cash flows.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical study data from completed or ongoing clinical studies for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed.

Risks related to intellectual property

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to intellectual property license agreements with third parties, including with respect to somavaratan, and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we may not be able to develop and market any product that is covered by these agreements. For example, we license substantially all of the intellectual property relating to somavaratan from Amunix, and the loss of our license agreement with Amunix would therefore materially adversely affect our ability to proceed with any development or potential commercialization of our product candidates as currently planned. Amunix has the right to terminate the license upon 30 days' written notice with respect to a particular target and the related products if (i) during any consecutive 18 month period our cumulative funding of research, development and commercialization activities in

respect of such target is not at least $250,000, in which case we would have the right to extend the applicable 18 month period by paying Amunix $150,000; or (ii) if we do not use commercially reasonable measures to develop and commercialize licensed products based on such target. Termination of this license, or reduction or elimination of our licensed rights under it or any other license, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business and financial condition.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we license, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business. In some cases we do not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents. We are also required to reimburse Amunix for certain costs incurred in prosecuting, maintaining, defending and enforcing the licensed patents.

Our ability to successfully commercialize our technology and products may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

We license substantially all of the intellectual property relating to somavaratan from Amunix. We do not presently own any issued patents or pending patent applications, and our license agreement with Amunix provides that inventions relating to somavaratan are owned by Amunix. We are therefore dependent on Amunix to apply for, prosecute, maintain, defend and, in some cases, enforce the patent rights necessary to conduct our business. However, we cannot be certain this will be done in a manner consistent with the best interests of our business. The process of applying for patents is expensive and time-consuming, and Amunix may not, or may not be able to, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or Amunix will fail to identify patentable aspects of our respective research and development output before it is too late to obtain patent protection. While Amunix has obtained a number of patents relating to the XTEN technology, and applied for a number of other patents relating to the XTEN technology in general, and somavaratan in particular, we cannot assure you that any pending or future applications will result in issued patents, and the existing Amunix patents that we license, and any future patents they obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. Under our license agreement with Amunix, we are obligated to use commercially reasonable efforts to develop and commercialize certain products that we license from Amunix and to maintain minimum rates of spending on research, development and commercialization. In exchange, we retain a limited, exclusive license from Amunix to relevant patents and know-how related to XTEN technology. If we fail to fulfill our obligations under the agreement, Amunix could terminate the agreement.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of the patent rights we rely on are highly uncertain. Pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the patents we rely on or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that our licensors were the first to make the inventions claimed in our licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent.

Even if the patent applications we rely on issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the patents we rely on may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

Finally, certain of Amunix's activities have been funded, and may in the future be funded, by the U.S. government. When new technologies are developed with U.S. government funding, the government obtains certain rights in any resulting patents, including the right to a nonexclusive license authorizing the government to use the invention. These rights may permit the government to disclose our confidential information to third parties and to exercise "march-in" rights to use or allow third parties to use Amunix's patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, U.S. government-funded inventions must be reported to the government, U.S. government funding must be disclosed in any resulting patent applications, and Amunix's rights in such inventions may be subject to certain requirements to manufacture products in the United States.

We may become involved in legal proceedings to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate the patents we rely on, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent we are asserting is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patents we are asserting do not cover the technology in question. An adverse result in any litigation proceeding could put one or more patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Interference or derivation proceedings provoked by third parties or brought by the United States Patent and Trademark Office, or USPTO, or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. We or our licensers may become involved in proceedings, including oppositions, interferences, derivation proceedings inter partes reviews, patent nullification proceedings, or re-examinations, challenging our patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain. For example, Novo Nordisk A/S filed oppositions to two issued European patents relating to the XTEN technology. Both of the oppositions resulted in adverse initial decision by the European Patent Office that are currently under appeal. The patents remain in effect until complete adjudication of the appeal, which typically is a multi-year process. An adverse final determination in any such proceeding could reduce the scope of, or invalidate, our important patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Our business also could be harmed if a prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we hold material service agreements with certain parties, including Amunix, and disagreements may therefore arise as to the ownership of any intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and/or management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. Third parties may assert infringement claims against us based on existing or future intellectual property rights. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing our products and technology. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license,

it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position.

In addition to patent protection, we rely upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market. We seek to protect our confidential proprietary information, in part, by entering into confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. These agreements are designed to protect our proprietary information, however, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to the same extent as the laws of the United States. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business.

We may not be able to protect and/or enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive to us and to our licensors. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our products in jurisdictions where we or our licensors do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost to us and divert our efforts and attention from other aspects of our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we license;
- Our licensors or collaborators might not have been the first to make the inventions covered by an issued patent or pending patent application;
- Our licensors or collaborators might not have been the first to file patent applications covering an invention;
- Others may independently develop similar or alternative technologies or duplicate any of our or our licensors' technologies without infringing our intellectual property rights;
- Pending patent applications may not lead to issued patents;
- Issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop or in-license additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid by us and/or our licensors to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the licensed patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and those technologies licensed to us and this circumstance would have a material adverse effect on our business.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents.

In March 2013, under the America Invents Act, or AIA, the United States moved to a first-to-file system and made certain other changes to its patent laws. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. Accordingly, it is not yet clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, all of which could have a material adverse effect on our business and financial condition.

If our third party licensors do not obtain a patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, if any, one or more of the U.S. patents covering our approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we or our licensors may not be granted patent term extension either in the United States or in any foreign country in the event, for example, we or our licensors fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we or our licensors are unable to obtain patent term extension or restoration, or the term of any such extension is less than requested, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks related to government regulation

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of our 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. Neither we nor our collaboration partners are permitted to market our product candidates in the United States until we receive approval of a BLA from the FDA. Neither we nor our collaboration partners have submitted an application or received marketing approval for somavaratan or any future product candidates. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

Prior to receiving approval to commercialize any of our product candidates in the United States or abroad, we and our collaboration partners must demonstrate with substantial evidence from well-controlled clinical studies, and to the satisfaction of the FDA and other regulatory authorities abroad, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical studies can be interpreted in different ways. Even if we and our collaboration partners believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our product candidates to humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical studies of our product candidates and result in the FDA or other regulatory authorities denying approval of our product candidates for any or all targeted indications.

Regulatory approval of a BLA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical studies, or perform additional preclinical studies and clinical studies. The number of preclinical studies and clinical studies that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to, the following:

- a product candidate may not be deemed safe or effective;
- FDA officials may not find the data from preclinical studies and clinical studies sufficient;
- the FDA might not approve our or our third-party manufacturer's processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

In addition, the statutes and regulations that define the time lines and criteria for approval of drugs and biologics are subject to change by Congress and the responsible administrative agencies. For example, the Prescription Drug User Fee Act (PDUFA) authorizes the FDA to collect fees and use them for the review of human drug applications (including BLAs) and defines the review time targets for such applications. The current legislative authority for PDUFA expires in September 2017. New legislation will be required for the FDA to continue collecting prescription drug user fees in future fiscal years and for manufacturers to have clarity regarding the time the FDA will spend reviewing BLAs and similar submissions. If PDUFA reauthorization is not completed, the

review time for our BLA for somavaratan could be significantly longer than currently expected, which could delay potential marketing approval and launch.

If somavaratan or any future product candidates fail to demonstrate safety and efficacy in clinical studies or do not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once regulatory approval has been granted, the approved product and its manufacturer are subject to continual review by the FDA and/or non-U.S. regulatory authorities. Any regulatory approval that we or any future collaboration partners receive for somavaratan or any future product candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the product. In addition, if the FDA and/or non-U.S. regulatory authorities approve somavaratan or any future product candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. In addition, manufacturers of our drug products are required to comply with cGMP regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

The regulatory requirements and policies may change and additional government regulations may be enacted with which we may also be required to comply. 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 in other countries. If we are not able to maintain regulatory compliance, we may not be permitted to market our future products and our business may suffer.

Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We intend to seek a distribution and marketing partner for somavaratan outside the United States and may market future products in international markets. In order to market our future products in regions such as the European Economic Area, or EEA, Asia Pacific, or APAC, and many other foreign jurisdictions, we must obtain separate regulatory approvals.

For example, 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 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. In Japan, the PMDA of the Ministry of Health Labour and Welfare, or MHLW, must approve an application under the Pharmaceutical Affairs Act before a new drug product may be marketed in Japan.

We have had limited interactions with foreign regulatory authorities. 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. Moreover, clinical studies 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 obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the ACA, was enacted in 2010. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The ACA, among other things:

- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs," effective 2011;
- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%, effective 2011;
- could result in the imposition of injunctions;
- requires collection of rebates for drugs paid by Medicaid managed care organizations;
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable branded 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; and
- creates a process for approval of biologic therapies that are similar or identical to approved biologics.

While the U.S. Supreme Court upheld the constitutionality of most elements of the ACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the ACA. At this time, it remains unclear whether there will be any changes made to the ACA, whether to certain provisions or its entirety. We cannot assure you that the ACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. Although the Budget Resolution is not a law, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed. Thus, the full impact of the ACA on our business remains unclear.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by the sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare reductions went into effect. We cannot predict whether any additional legislative changes will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing

efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical study protocols to reflect these changes. Amendments may require us to resubmit our clinical study protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical study. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance and/or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical studies and the drug approval process. Data from clinical studies may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical studies before completion, or require longer or additional clinical studies that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Given the serious public health risks of high profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce 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 federal healthcare programs, such as the Medicare and Medicaid programs;
- indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The ACA, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition,

the ACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Risks related to ownership of our common stock

Our stock price may be volatile, and investors in our common stock could incur substantial losses.

Our stock price has fluctuated in the past and may be volatile in the future. From January 1, 2015 through July 31, 2017 the reported sale price of our common stock has fluctuated between $6.41 and $23.46 per share. The stock market in general and the market for biotechnology 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, investors may experience losses on their investment in our common stock. The market price for our common stock may be influenced by many factors, including the following:

- the success of competitive products or technologies;
- results of clinical studies of somavaratan or future product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- the other risks described in this "Risk factors" section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Our executive officers, directors and principal stockholders will continue to maintain the ability to control or significantly influence all matters submitted to stockholders for approval.

As of July 31, 2017, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock, in the aggregate, beneficially owned shares representing approximately 68.8% of our common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, will control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the other rules and regulations of the Securities and Exchange Commission, or SEC, and the rules and regulations of The NASDAQ Global Select Market, or NASDAQ. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel are devoting and will continue to need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees, or as executive officers

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, 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, as required by Section 404 of the Sarbanes-Oxley Act. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate condensed consolidated financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

In connection with our preparations for becoming a public company, we identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our condensed consolidated financial statements. If we fail to remediate one or more of our material weaknesses in the future or if we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of condensed consolidated financial statements in accordance with U.S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim condensed consolidated financial statements will not be prevented or detected on a timely basis.

Prior to the completion of our initial public offering, we were a private company with limited accounting personnel and other resources to address our internal control over financial reporting. During the course of preparing for our initial public offering, we determined that material adjustments to various accounts were necessary, which required us to restate the financial statements as of and for the years ended December 31, 2012 and 2011 and for the period from inception (December 10, 2008) through December 31, 2012 that had been previously audited by another independent audit firm. These adjustments leading to a restatement of those financial statements led us to conclude that we had a material weakness in internal control over financial reporting as of December 31, 2012. The material weakness that we identified was that we did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our structure and financial reporting requirements.

This material weakness contributed to adjustments to previously issued financial statements principally, but not limited to, the following areas: equity accounting in connection with our issuance of Series A and B convertible preferred stock and period-end cutoff for clinical trial related expenses.

While we have been successful in our efforts to remediate this particular material weakness we cannot assure you that we will be able to prevent or remediate any additional weaknesses in the future, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows. If we are unable to successfully prevent or remediate any additional material weaknesses in the future, and if we are unable to produce accurate and timely consolidated financial statements, including our filing of quarterly reports with the SEC on a timely and accurate basis, our stock price may be adversely affected and we may be unable to maintain compliance with applicable NASDAQ listing requirements.

An active trading market for our common stock may not be maintained.

Our common stock is currently traded on NASDAQ, but we can provide no assurance that we will be able to maintain an active trading market for our shares on NASDAQ or any other exchange in the future. If there is no active market for our common stock, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may cease to publish research on our company at any time in their discretion. If one or more of these analysts cease coverage of our company, or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline. In addition, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If our operating results fail to meet the forecast of analysts, our stock price would likely decline.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

- our board of directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our board of directors has the right to elect directors 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;
- our stockholders are not able to act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock are not able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors, the chairman of the board, the chief executive officer or the president;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can 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 our company; and
- our board of directors are able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

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

Our employment arrangements with our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us, which could harm our financial condition or results.

Certain of our executive officers are parties to employment or other agreements or participants under plans that contain change in control and severance provisions providing for aggregate cash payments for severance and other benefits and acceleration of vesting of stock options in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

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

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

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

None

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Versartis, Inc.	8-K	001-36361	3.1	03/26/2014
3.2	Amended and Restated Bylaws of Versartis, Inc.	S-1/A	333-193997	3.4	03/06/2014
4.1	Form of Stock Certificate	10-Q	001-36361	4.1	05/14/2014
10.1*^	Amended Boehringer Ingelheim Technology Transfer, Clinical Supply Agreement by and between Versartis, Inc. and Boehringer Ingelheim dated October 23, 2012				
10.2*^	Amended Amunix License Agreement by and between Versartis, Inc. and Amunix Operating, Inc. dated March 22, 2016				
31.1*	Certification required by Rule 13a-14(a) or Rule 15d-14(a).				
31.2*	Certification required by Rule 13a-14(a) or Rule 15d-14(a).				
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).				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed Herewith.
^ Confidential treatment has been requested as to certain portions, which portions have been separately filed with the Securities and Exchange Commission.
\+ This certification accompanies the Quarterly Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

VERSARTIS, INC.
(Registrant)

Date: August 7, 2017

/s/ Jay Shepard
Jay Shepard
Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2017

/s/ Joshua T. Brumm
Joshua T. Brumm
Chief Operating Officer & Chief Financial Officer
(Principal Financial and Accounting Officer)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.1

Amendment No. 2
(hereinafter the "Amendment No. 2")

to the Technology Transfer, Clinical Supply Agreement
dated October 23, 2012,
(hereinafter the "Agreement")

between

Versartis, Inc.
4200 Bohannon Drive,
Suite 250,
Menlo Park, CA 94025
USA

(hereinafter called "VERSARTIS") and

Boehringer Ingelheim Biopharmaceuticals GmbH
Binger Straβe 173
55216 Ingelheim/Rhein
Germany

(hereinafter called "BI").

Preamble

Whereas, the Agreement has been concluded between VERSARTIS and BI's Affiliated Company Boehringer Ingelheim RCV GmbH & Co KG ("BI RCV") regarding the manufacture of VRS-317. Originally, the Services anticipated under the Agreement did only cover the manufacture of VRS-317 as bulk drug substance.

Whereas, effective October 1, 2013, VERSARTIS and BI RCV amended the Agreement to change some of the exhibits to the Agreement, and to add certain work packages that included the manufacture of drug product in order for BI RCV to provide additional cGMP fill and finish work and additional bulk drug substance services.

Whereas, BI RCV assigned the Agreement, as amended, with all rights and obligations to BI with effect from January 1st, 2014, with the exception of the Quality Agreement, which remained unaffected and for which BI RCV continued to assume all rights and obligations related to it.

Whereas, Versartis wishes to have BI perform additional Drug Substance Services including but not limited to development and optimization and manufacture of additional Phase III Drug Substance and performance of PPQ Runs for the validation of Drug Substance at the Facility.

Whereas, Versartis wishes to have BI perform additional Services for Drug Product, including but not limited to the establishment of the filling process for pre-filled syringes (PFS) and vials at BI's Affiliated Company Boehringer Ingelheim Pharma GmbH & Co. KG ("BI Pharma").

Whereas, Versartis wishes to have BI manufacture, for VERSARTIS" clinical Phase III studies two different forms of Drug Product, and accordingly, BI is preparing to fill Drug Substance into Drug Product vials at the Facility in Vienna (BI RCV) for Phase III only, and in parallel, BI is preparing for the establishment of the filling process in PFS (Commercial Manufacturing Process) including PPQ runs for the validation of Drug Product at the Facility in Biberach (BI Pharma).

NOW THEREFORE, the Parties agree that hereby (i) certain definitions and warranties of the Agreement need to be amended, and (ii) the Appendices 3, 4 and 5 of the Agreement shall be updated to reflect these additional cGMP Services.

Except as otherwise indicated, defined terms in this Amendment No. 2 have the same meaning as in the Agreement, as amended.

1. Subsections 1.14 through 1.42 are deleted in their entirety and replaced by the following Subsections 1.14 through 1.47:

1.14 Commercial Manufacturing Process
shall have the meaning as defined in Section 1.31. For the purpose of this Agreement, the term Commercial Manufacturing Process refers to the Manufacturing Process that BI will use to manufacture commercial Drug Substance and commercial Drug Product in PFS or vials (i.e., Product that is marketed, distributed, and sold or intended to be sold). The term Commercial Manufacturing Process does not include Drug Product intended to be used for clinical trials.

1.15 Confidential Information
shall mean any information and materials disclosed by a Party or an Affiliated Company of such Party to the other Party or its Affiliated Company(ies), which information includes, but is not limited to: all know-how, trade secrets, inventions, non-public patent applications, processes, concepts, technology regarding the manufacture of biopharmaceuticals, and experimental methods as well as information concerning the Disclosing Party's and/or its Affiliated Companies' financial situation, customers, business plans, and its or its Affiliated Companies' research and product designs and other data and information disclosed or exchanged under the CDA and this Agreement; as well as the terms of the CDA and of this Agreement.

1.16 CUSTOMER Deliverables
shall mean the [*] and any other material and documents to be provided by CUSTOMER to BI as listed in detail in Appendix 1.

1.17 CUSTOMER Improvements
shall have the meaning as set forth in Section 8.2.1.

1.18 Direct Competitor
shall mean for BI: a third party which is exclusively or primarily in the business of offering and providing services for the manufacture of biopharmaceuticals for the benefit of other companies (unless such other companies are solely affiliated companies of such other company). For the sake of clarity, "Direct Competitor" shall not include a third party such as [*] which is primarily in the business of developing and commercializing pharmaceutical products but which may also contract manufacturing services; and for CUSTOMER: a third party developing, manufacturing or selling a pharmaceutical product for the same indication as the Product.

1.19 Disclosing Party
in the capacity of disclosing Confidential Information and Know-How, each Party is referred to as the Disclosing Party.

1.20 Drug Product
shall mean the unlabeled final dosage form of a pharmaceutical medicine containing Drug Substance formulated with selected excipients and packaged for the end user (i.e., vials, syringes), as listed in Exhibit 1 to the QA.

1.22 Drug Substance
shall mean an active pharmaceutical ingredient in formulated bulk form as listed in Exhibit 1 to the QA, which is subsequently used to produce Drug Product.

1.23 Effective Date
shall mean the date of commencement of this Agreement as mentioned on the cover page thereof.

1.24 Facility
shall mean the biotech buildings and all other buildings located at [*], used by BI and/or its Affiliated Companies BI RCV and/or BI Pharma in performance of the Project.

1.25 Improvements
shall mean all discoveries and inventions, and all modifications, derivatives and improvements of Background IP or new uses thereof (whether or not protectable under patent, trademark, copyright or similar laws) that are discovered, invented, developed or reduced to practice in the performance of this Agreement.

1.26 Initial Process
shall mean the initial process for manufacturing Product developed and owned or in-licensed by CUSTOMER and reflected by the parameters, standards and preliminary specifications as summarized in Appendix 1 and Appendix 5.

1.27 Intellectual Property Rights
shall mean any and all now known or hereafter existing: (i) rights associated with works of authorship, including copyrights and moral rights; (ii) know-how and trade secret rights; (iii) patent rights and industrial property rights (including trademarks); (iv) other proprietary rights in all inventions (whether or not patentable), discoveries, methods, processes, techniques, specifications, protocols, schematics, diagrams, reagents, compounds, samples, formulation, data, circuit designs, design layout, databases, data, and other forms of technology; and (v) all registrations, applications, renewals, and extensions of the foregoing, in each case in any jurisdiction throughout the world, including, but not limited to, inventor's certificates, utility models, substitutions, confirmations, reissues, re-examinations, renewals or any like governmental grants for protection of inventions; and any pending application for any of the foregoing, including any continuation, divisional, substitution, additions, continuations-in-part, provisional and converted provisional applications, as well as extensions and supplementary protection certificates based thereon.

1.28 Knowledge
shall mean that which a Party knows or should have known following that inquiry a reasonable person would have made in light of the facts and circumstances.

1.29 Latent Defects
shall mean non-conformance of the Product with the Specifications other than Obvious Defects.

1.30 Losses
shall have the meaning set forth in Section 7.4a.

1.31 Manufacturing Process
shall mean the Initial Process adapted to the Facility and/or optimized or developed by BI during the performance of the Project. After the PPQ Runs, the Manufacturing Process shall be referred to as

"Commercial Manufacturing Process", if used to manufacture Product intended to be marketed, distributed, and sold or intended to be sold.

1.32 Manufacturer's Release
shall mean BI's release of a cGMP-conforming Batch of Product (either as drug substance or in the final dosage form as drug product- whichever is the case) in accordance with the QA.

1.33 Obvious Defects
shall mean any non-conformance of the Product with the Specifications, which is visible or easily detectable without any analysis in a laboratory.

1.34 Process Description
shall mean a controlled document of BI, approved by authorized technical and quality representatives of both Parties, that documents the general outline of the respective Manufacturing Process. It includes all relevant process parameters to be met and equipment and raw materials to be used.

1.35 "PPQ Runs"
shall mean the Manufacturing Process performance qualification Batches which will be used as basis for the Process Validation.

1.36 "Process Validation"
shall mean the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product.

1.37 Product
shall mean the pharmaceutical product described in Appendix 1 produced using the Manufacturing Process and formulated either as bulk Drug Substance or in final dosage form as Drug Product.

1.38 Project
shall mean the performance of the Services, including without limitation the development of the Manufacturing Process, if any, for the Product.

1.35 Project Fees
shall have the meaning specified in Section 3.1 hereof.

1.39 Project Manager
shall have the meaning specified in Section 2.2.1 hereof.

1.40 Project Plan
shall mean the plan describing the Services to be performed by BI (by itself or its Affiliated Companies) under the Project, including the (initial) Project timeline in Appendix 3, attached to this Agreement as Appendix 2.

1.41 Project Team
shall have the meaning specified in Section 2.2.2 hereof and at the Effective Date shall consist of the persons listed in. Appendix 6.

1.42 QA
shall mean the Quality Agreement attached hereto as Appendix 7, as modified from time to time.

1.43 Receiving Party
in the capacity of receiving Confidential Information and know-how, each Party is referred to as the Receiving Party.

1.44 Representatives
shall mean a Party's Affiliated Companies and its own, as well as its Affiliated Companies' officers, employees and agents.

1.45 Service(s)
shall mean those certain services performed by BI under this Agreement as outlined in the Project Plan in Appendix 2.

1.46 Specification(s)
shall mean all the specifications and tests, analytical methods and/or limits, and the results thereof, as applicable, agreed by the Parties and within which the Product has to conform to be considered acceptable by CUSTOMER for clinical use. The Parties are in agreement, that pursuant to Section 2.7 in the first instance preliminary specifications shall be contained in Appendix 5 to this Agreement and shall thereafter be fixed to final Specifications as Appendix to the QA in accordance with Section 2.7. Such specifications may be amended as necessary and agreed in writing between the parties. The current clinical specifications shall serve as preliminary Specifications for the Commercial Manufacturing Process which shall be defined in the commercial supply agreement.

1.47 Steering Committee
shall have the meaning specified in Section 2.2.3 hereof.

2. Section 4.2.2 is deleted in its entirety and replaced by the following:

"4.2.2 Cancellation or Postponement of Order for subsequent clinical supply:

Subject to Section 4.2.3, below:

If CUSTOMER cancels or postpones any campaign set forth in the Project Plan for the manufacture of Drug Substance for subsequent clinical supply less than [*] but more than [*] prior to the date on which [*], then CUSTOMER is required to pay [*] of the Project Fees for such campaign.

If CUSTOMER cancels or postpones any campaign set forth in the Project Plan for the manufacture of Drug Substance for subsequent clinical supply less than [*] but more than [*] prior to the date on which [*], then CUSTOMER is required to pay [*] of the Project Fees for such campaign.

If CUSTOMER cancels or postpones any campaign set forth in the Project Plan for the manufacture of Drug Product filled in vials or in pre-filled syringes for subsequent clinical supply less than [*] but more than [*] prior to the date on which [*], then CUSTOMER is required to pay [*] of the Project Fees for such campaign.

Cancellation or postponement of manufacture of Drug Substance campaign less than [*] but more than [*] prior to the date on which [*] results in a payment obligation of CUSTOMER of [*] of the Project Fees for such campaign and [*] for the cancellation or postponement of manufacture of Drug Product filled in vials or in pre-filled syringes.

Cancellation or postponement of manufacture of Drug Product filled in vials or in pre-filled syringes less than [*] prior to the date on which [*] results in a payment obligation of CUSTOMER of [*] of the Project Fees for such campaign.

TABLE SUMMARIZING CANCELLATION/POSTPONEMENT FEES:

CANCELLATION OR POSTPONEMENT LESS THAN	DRUG SUBSTANCE	DRUG PRODUCT FILLED IN VIALS	DRUG PRODUCT FILLED IN PRE-FILLED SYRINGES
	prior to the date on which [*]		
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]]

3. Section 2.7 is deleted in its entirety and replaced by the following:

"2.7 Nature of the Project

As the Product with the optimized Phase III Manufacturing Process for Drug Substance and the prefilled syringes or vials for Drug Product has never been produced by BI at the Facility, CUSTOMER acknowledges that the Project is experimental in nature and that no favourable or useful Product(s) can be assured by BI. Therefore, the Parties have agreed to [*] as set forth in Appendix 5 of the Agreement.

The new technology transfer phase shall be completed with the first successful manufactured Batch at [*] scale (e.g. [*]) that meets the Product Specifications as mutually agreed by the Parties. Notwithstanding the foregoing, the Parties are in agreement that [*] shall be performed [*].

After [*] initial manufacturing runs [*], the Parties shall in good faith agree on a revision (if necessary) of the preliminary specifications that shall then be the respective Specifications for the Product in the respective clinical Phase manufactured in subsequent manufacturing runs at such scale, and, provided that the Manufacturing Process has not been materially changed the Project shall no longer be considered experimental in nature and the obligation to meet the respective Specification shall apply to all future manufacturing runs at such scale".

4. Section 5.1 (b) is deleted in its entirety and replaced by the following:

"b. CUSTOMER shall prepare the draft chemistry, manufacturing and controls section of any regulatory filing supporting the clinical development of the Product for the USA and EU, with the exception of any requirements for combination products under 21 CFR PART 4 and similar requirements from non-U.S. regulatory authorities. BI will timely provide CUSTOMER with all necessary information to comply with 21 CFR PART 4 and 21 CFR § 820. BI shall timely perform reviews of the chemistry, manufacturing and controls section of any such regulatory filing for accuracy of content of such section prior to filing by CUSTOMER with the relevant regulatory authorities".

5. Section 6.3 (e) is deleted in its entirety and replaced by the following:

[BI hereby represents and warrants ("gewährleistet") that:]

e. "each Batch where a Manufacturer's Release has been performed will be manufactured in accordance with cGMP and on the date of BI's Manufacturer's Release shall comply with the Specifications".

3. The Parties agree that Appendix 2 ("Project Plan (BI Services and Prices)") as attached to the Agreement, as amended, has been further amended by Change Order #47 effective March 17, 2015 and Change Order #37 effective as of July 10, 2015. Change Order #47, Change Order #37 and any

subsequent Change Orders and Proposals shall be governed by the Agreement, as amended, including this Amendment No. 2.

4. The Parties agree that the additional cGMP services set forth in Change Orders #47 and #37 are considered part of the Services and firmly ordered.

5. The Parties agree that the clinical specifications in Exhibit C shall serve as preliminary Specifications for the Commercial Manufacturing Process which shall be defined in the commercial supply agreement.

6. Equally, the Parties agree that Appendices 3, 4 and 5, as attached to the Agreement (as amended), shall be updated and amended with Exhibits A, B, and C to this Amendment No. 2.

7. Appendix 7 (QA) as attached to the Agreement (as amended), shall be updated and be replaced in its entirety by Exhibit D to this Amendment No. 2, which shall become the new Appendix 7.

8. This Amendment No. 2 shall take effect as of November 18, 2015 ("Effective Date") and as far as not amended herein, the Agreement, as amended by Amendment No. 1, remains in full force and effect.

Signatures on the following page.

Ingelheim, November 18, 2015
Boehringer Ingelheim Biopharmaceuticals GmbH

/s/ Alois Konrad
Alois Konrad
VP, Business & Contracts

/s/ Andreas Felder
Dr. Andreas Felder
Head, Corporate Legal Biopharmaceuticals

Menlo Park, CA, November 30, 2015
Versartis, Inc.

/s/ Jay Shepard
Jay Shepard
CEO

List of Exhibits:

Exhibit A:	Project Plan and Timeline
Exhibit B:	Payment Schedule
Exhibit C:	Product Testing Specifications
Exhibit D:	QA: To Be Added

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit A: Project Plan and Timeline

[*] (1 page omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit B: Payment schedule covering all services

[*] (1 page omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit C: Product Testing Specifications

[*] (2 pages omitted)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit D: OA

To be added after signature.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.2

AMUNIX OPERATING INC.
500 Ellis Street
Mountain View, CA 94043

May 12, 2016

Versartis, Inc.
4200 Bohannon Drive
Suite 250
Menlo Park, CA 94025

Attention: Senior Vice President, Legal and Compliance

Re: Amendment to License Agreement

Dear Ladies and Gentlemen,

This Letter Agreement ("Letter Agreement") is made effective as of March 22, 2016 ("Amendment Effective Date") by and between Versartis, Inc., a Delaware corporation ("Licensee") and Amunix Operating, Inc., a Delaware corporation ("Licensor"). This Letter Agreement makes reference to that certain Second Amended and Restated Licensing Agreement between Amunix and Versartis, dated December 30, 2010, as amended by that certain Amendment No. 1 and Amendment No. 2 (collectively, the " License Agreement").

In accordance with Section 4.1(c) of the License Agreement, Licensee has been reimbursing Licensor for [*] of the filing, prosecution and maintenance costs with respect to the Licensed Patents that are not primarily applicable to the Licensed Product. It is mutually agreed by the parties that, as of the Amendment Effective Date, the Licensee shall reimburse Licensor for [*] of the filing, prosecution and maintenance costs associated with the granted patents in the [*].

All specific expenditures shall be expressly approved by Licensee before the obligations are incurred and Licensee shall be a participant in determining prosecution strategy for any [*]. Further, it is mutually agreed by the parties, that Licensor will provide Licensee with copies of all official actions and other communications related to the [*] received by the Licensor from or to applicable patent authorities in a timely manner and that the Licensee shall have the right to provide comments and suggested edits to claim sets and responses to [*] Actions and opposition submissions. To date, Licensee has agreed to reimburse costs of:

- [*]

Licensee shall continue to reimburse costs associated with Licensed Patents that are not primarily applicable to the Licensed Product at the rate of [*] for all other patent families and all territories in the world, including the United States.

The execution of this Letter Agreement constitutes a representation and warranty by the parties that each has the full legal right, power, and authority to enter into this Letter Agreement and to be bound by its provision in accordance with its terms. This Letter Agreement shall be effective only upon execution by each of the parties hereto and shall be binding and inure to the benefit of the parties and their respective successors and assigns, and, in any event, shall continue to be binding on the parties. This Letter Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument. This Letter Agreement may be amended only by a writing signed by the parties. No person or entity is intended or shall be deemed or determined to be a third party beneficiary of this Letter Agreement. This Letter Agreement shall be governed by, and construed in accordance with, the laws of the State of California. This Letter Agreement constitutes the entire agreement between the parties and supersedes any prior understandings, agreements, or representations by or between the parties, written or oral, express or implied regarding the matters contained herein.

Sincerely,

Amunix Operating Inc.

By: /s/Volker Schellenberger
Name: Volker Schellenberger
Title: Chief Executive Officer

ACKNOWLEDGED AND ACCEPTED:

Versartis, Inc.

By: /s/Shane Ward
Name: Shane Ward
Title: Senior Vice President, Legal and Compliance

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 31.1

Certification of President and Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jay Shepard, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Versartis, Inc.

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

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

4. The registrant's other certifying officer(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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 7, 2017

/s/ Jay Shepard
Jay Shepard
Chief Executive Officer

Exhibit 31.2

Certification of President and Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Joshua Brumm, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Versartis, Inc.

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

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

4. The registrant's other certifying officer(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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 7, 2017

/s/ Joshua T. Brumm

Joshua T. Brumm
Chief Operating Officer and Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Jay Shepard, Chief Executive Officer of Versartis, Inc. (the "Company"), and Joshua Brumm, Chief Operating Officer and Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2017, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: August 7, 2017

In Witness Whereof, the undersigned have set their hands hereto as of the 7th day of August, 2017.

/s/ Jay Shepard
Jay Shepard
Chief Executive Officer

/s/ Joshua T. Brumm
Joshua T. Brumm
Chief Operating Officer and Chief Financial Officer