Versartis, Inc.
Form 10-Q
August 08, 2018

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, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 001-36361

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)

1020 Marsh Rd

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, 2018, there were 36,240,673 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, 2018

PART I. FINANCIAL 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, 2018	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	$67,776	$ 81,146
Prepaid expenses and other current assets	686	562
Total current assets	68,462	81,708
Restricted cash	2,388	2,383
Property and equipment, net	680	798
Build-to-suit lease asset	8,770	8,888
Total assets	80,300	93,777
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$804	$ 1,500
Accrued liabilities	3,234	4,093
Total current liabilities	4,038	5,593
Build-to-suit lease obligation	7,324	5,428
Total liabilities	11,362	11,021
Commitments and contingencies (Note 5)		
Stockholders' equity		
Common stock, $0.0001 par value, 100,000,000 shares authorized at June 30, 2018 and December 31, 2017; 36,240,673 and 35,938,126 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	4	4
Additional paid-in capital	461,995	456,984
Accumulated deficit	(393,061)	(374,232)
Total stockholders' equity	68,938	82,756
Total liabilities and stockholders’ equity	$80,300	$ 93,777

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

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VERSARTIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses				
Research and development	$3,438	$28,618	$7,038	$50,622
General and administrative	6,003	7,572	10,920	15,228
Total operating expenses	9,441	36,190	17,958	65,850
Loss from operations	(9,441)	(36,190)	(17,958)	(65,850)
Interest income	249	242	442	441
Other income (expense), net	(656)	(521)	(1,313)	(782)
Net loss before provision for income taxes	$(9,848)	$(36,469)	$(18,829)	$(66,191)
Provision for income taxes	—	128	—	128
Net loss	$(9,848)	$(36,597)	$(18,829)	$(66,319)
Net loss per share - basic and diluted	$(0.27)	$(1.04)	$(0.52)	$(1.89)
Weighted-average common shares used to compute basic and diluted net loss per share	36,134	35,316	36,010	35,001

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,	
	2018	2017
Cash flows from operating activities		
Net loss	$(18,829)	$(66,319)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	236	104
Stock-based compensation expense	4,976	7,522
Changes in assets and liabilities		
Prepaid expenses and other assets	(124)	(7,124)
Accounts payable	(695)	1,194
Accrued and other liabilities	(860)	8,063
Income taxes payable	—	(247)
Net cash used in operating activities	(15,296)	(56,807)
Cash flows from investing activities		
Purchase of property and equipment	—	(1,009)
Inducement on build-to-suit lease obligation	1,896	—
Net cash used in investing activities	1,896	(1,009)
Cash flows from financing activities		
Proceeds from issuance of common stock in connection with employee benefit plans	35	2,399
Net cash provided by financing activities	35	2,399
Net increase (decrease) in cash, cash equivalents, and restricted cash	(13,365)	(55,417)
Cash, cash equivalents, and restricted cash at beginning of period	83,529	201,153
Cash, cash equivalents, and restricted cash at end of period	$70,164	$145,736
Supplemental disclosure		
Income taxes paid	$—	$375
Supplemental disclosure of noncash items		
Build-to-suit leasehold improvements	$5,428	$1,219
Build-to-suit lease transaction	$—	$8,174

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

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VERSARTIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (unaudited)

VERSARTIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. Formation and Business of the Company

Versartis, Inc., or the Company, was incorporated on December 10, 2008 in the State of Delaware. The Company has been an endocrine-focused biopharmaceutical company that was developing a long-acting recombinant human growth hormone for the treatment of growth hormone deficiency.

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.

In September 2017, the Company announced that the VELOCITY Phase 3 clinical trial of somavaratan in pediatric growth hormone deficiency, or GHD, failed to meet its primary endpoint of non-inferiority. All ongoing clinical trials of somavaratan have concluded and currently the Company does not intend to further develop somavaratan.

In June 2018, the Company entered into a merger agreement with Aravive Biologics, Inc. to form a clinical stage, Nasdaq-listed company, based in Houston, Texas, focused on the development of innovative oncology therapeutics. Aravive Biologics is a privately held clinical stage biopharmaceutical company developing novel, highly selective therapies designed to treat serious cancers and certain fibrotic diseases. Under this merger agreement, Aravive will merge with a wholly owned subsidiary of Versartis in an all-stock transaction. Following the proposed merger, Versartis and Aravive equity holders are each expected to own approximately 50 percent of the combined company. This transaction is expected to close during the second half of 2018, subject to approval by the stockholders of both companies and the satisfaction or waiver of other customary closing conditions.

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, 2018, its results of operations three- and six- month periods ended June 30, 2018, and 2017, cash flows three- and six- months ended June 30, 2018, and 2017. The December 31, 2017 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, 2017 included in the Company's annual report on Form 10-K filed on March 6, 2018 with the U.S. Securities and Exchange Commission, or the 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, or 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, 2018 and as of December 31, 2017, and the results of operations and cash flows for the three- and six- month periods ended June 30, 2018 and 2017 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, 2018, the Company had a cash and cash equivalents balance of $67.8 million consisting of cash and cash equivalents 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 current business plan. As a result of the failure of the VELOCITY trial to meet its primary endpoint, the Company has implemented a number of cost-cutting measures, including a reduction in workforce of approximately two-thirds from September 2017. The Company’s expected cash needs for the foreseeable future have been significantly reduced with the current initiatives and termination of a number of supplier contracts, including

VERSARTIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (unaudited)

commercial contracts with our contract manufacturers. Since inception, the Company has incurred net losses and negative cash flows from operations. At June 30, 2018, the Company had an accumulated deficit of $393.1 million and working capital of $64.4 million. The Company expects to continue to incur losses from costs related to the proposed merger transaction and related 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, given the failure of the VELOCITY trial to meet its primary endpoint, 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 several financial institutions that management believes are of high credit quality. Such deposits may exceed federally insured limits.

The Company entered into forward foreign currency contracts that exposed it to credit risk to the extent that the counterparties potentially were unable to meet the terms of the agreement. The Company did, 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 did not expect material losses as a result of defaults by counterparties.

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 or a strategic transaction and dependence on key individuals and sole source suppliers.

Products developed by the Company require clearances from the U.S. Food and Drug Administration, or the FDA, the Pharmaceuticals Medicines and Devices Agency, or the 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 develop, launch and commercialize any product candidates for which it receives regulatory approval.

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, 2018 and December 31, 2017, 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.

Restricted Cash

Restricted cash includes cash and cash equivalents that is restricted through legal contracts, regulations or the Company's intention to use the cash for a specific purpose. The Company's restricted cash primarily relates to the letter of credit provided to its Landlord for the Company's headquarters in Menlo Park (as described in Note 5) to secure its obligations under the lease.

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.

VERSARTIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (unaudited)

Build-to-Suit Lease

In the Company's recent lease arrangement (as described in Note 5), the Company was 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 condensed consolidated balance sheet 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 condensed consolidated balance sheets representing the amounts paid by the lessor.

Upon completion of construction, the Company considered 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 where construction has been completed. The Company's assessment of the arrangement determined that they did not qualify for sale-leaseback accounting treatment; therefore the building asset remains on the Company's condensed consolidated balance sheets at its historical cost, and such asset is depreciated over its estimated useful life. 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 future net cash flows which 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, 2018 or December 31, 2017.

Fair Value of Financial Instruments

The carrying value of the Company's cash and cash equivalents, prepaid expenses, accounts payable and accrued liabilities approximate fair value due to the short-term nature of these items.

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 assets as of June 30, 2018. 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. These contracts are reported as Level II assets, however there were none outstanding as of June 30, 2018.

VERSARTIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (unaudited)

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, or 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. In September 2017, the Company announced that the VELOCITY Phase 3 clinical trial of somavaratan in pediatric growth hormone deficiency (GHD) failed to meet its primary endpoint of non-inferiority. All ongoing clinical trials of somavaratan have concluded and as such, there were no material preclinical and clinical trial accruals as of June 30, 2018.

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.

VERSARTIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (unaudited)

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,	
	2018	2017	2018	2017
Operating Expenses				
Research and development	$877	$1,501	$1,759	$2,982
General and administrative	1,278	2,157	3,217	4,540
Total	$2,155	$3,658	$4,976	$7,522

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. There was no difference between net loss and comprehensive loss for all periods presented.

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 became effective on January 1, 2018, has not had 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, also known as the screen test. If this threshold is met under the screen test, 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. In June 2018, the company entered into a proposed merger agreement with Aravive Biologics, Inc., where Aravive will merge with a wholly owned subsidiary of Versartis in an all-stock transaction. Under the agreement, Versartis will acquire Aravive's net assets under an asset acquisition. Substantially all of the fair value of the net acquired assets is concentrated in a single identifiable asset or a group of similar identifiable assets, and as such the set of net assets acquired is not deemed to be a business. The guidance, which has become effective for the Company on January 1, 2018, is expected to have a material impact on the Company's consolidated financial statements upon close of the proposed merger transaction between Versartis and Aravive as application of the screen test under the new guidance results in the transaction to be accounted for as an asset acquisition.

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 has become effective on a retrospective basis for the

VERSARTIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (unaudited)

Company on January 1, 2018. The Company retrospectively adjusted the prior periods presented in our consolidated statement of cash flows, which resulted in a reclassification of restricted cash of $2.4 million to the beginning and ending period balances of cash and cash equivalents at June 30, 2018. The following is a reconciliation of the captions in the consolidated balance sheet to the consolidated statements of cash flows (in thousands):

	As of June 30, 2018	December 31, 2017	June 30, 2017	December 31, 2016
Consolidated Balance Sheets				
Cash and cash equivalents	$67,776	$81,146	$143,358	$201,153
Restricted cash (included in other current assets)	2,388	2,383	2,378	—
Cash, cash equivalents and restricted cash in Consolidated Statements of Cash Flows	$70,164	$83,529	$145,736	$201,153

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 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 has adopted the new revenue standard as of January 1, 2018 using a modified retrospective application to each prior reporting period presented. Through June 30, 2018 the Company had no open contracts and previously recorded a cumulative inception to date total of $40.0 million of contract revenues at December 31, 2017 received from Teijin Limited under an exclusive license and supply agreement which was considered substantially complete as of December 31, 2017. The adoption did not have an effect on the Company’s consolidated financial statements on the adoption date and no adjustment to retained earnings as of January 1, 2018 was required.

3. Balance Sheet Components

Prepaid expenses and other current assets (in thousands)

	June 30, 2018	December 31, 2017
Preclinical and clinical [1]	$ 57	$ 261
Other	629	301
Total	$ 686	$ 562

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

VERSARTIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (unaudited)

Accrued Liabilities (in thousands)

	June 30, 2018	December 31, 2017
Payroll and related	$ 2,695	$ 2,058
Preclinical and clinical	82	1,694
Professional services	303	204
Other	154	137
Total	$ 3,234	$ 4,093

4. Fair Value Measurements

The Company's financial instruments consist principally of cash and cash equivalents, prepaid expenses, 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, 2018 (unaudited)			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$55,862	$55,862	$ —	$ —
	$55,862	$55,862	$ —	$ —

	Fair Value Measurements at December 31, 2017			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$62,428	$62,428	$ —	$ —
	$62,428	$62,428	$ —	$ —

5. Commitments and Contingencies

Facility Leases

In March 2017, the Company entered into an operating facility lease agreement for approximately 34,500 rentable square feet located at 1020 Marsh Road, Menlo Park, California (1020 Space) and for approximately 17,400 rentable square feet located on the second floor of the building located at 1060 Marsh Road. In September 2017, the Company terminated its lease specific to 1060 Marsh Road. The 1020 space serves as the Company's corporate headquarters.

The delivery of the 1020 Space to the Company occurred in April 2017. The 1020 Space lease commenced on August 8, 2017 for a period of 86 months, with one renewal option for a five-year term. The total obligation under this lease for the Company is approximately $18.4 million as of June 30, 2018.

As an inducement to enter the lease, the Landlord provided the Company with an approximately $1.9 million tenant improvement allowance for the 1020 Space. In January 2018, the Company received approximately $1.5 million, or 80% of the tenant improvement allowance. The remaining 20% of $0.4 million was received in May 2018. The Company has provided the Landlord with a letter of credit to secure its obligations under the lease in the initial amount of approximately $2.4 million, reported as restricted cash on the balance sheet, which is subject to reductions in future years if certain financial hurdles are met.

VERSARTIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (unaudited)

Future minimum lease payments under all of the Company's noncancelable operating and facility leases, as of June 30, 2018, were as follows (in thousands):

Year Ended December 31,	
2018	$1,363
2019	2,780
2020	2,854
2021	2,930
2022	3,009
Thereafter	5,449
Total	$18,385

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 began occupying the 1020 Space in August 2017. The lease has a term of 86 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 $20.0 million over the initial term of the lease. The obligation under this lease is approximately $18.4 million as of June 30, 2018. In connection with this lease, the landlord provided a tenant improvement allowance of approximately $1.9 million for the 1020 Space, for costs associated with the design, development and construction of the Company's improvements. The Company funded all costs incurred in excess of the tenant improvement allowance. As of June 30, 2018, the Company received all of the tenant improvement allowance. The $1.9 million inducement payment received increased the build-to-suit lease obligation to $7.3 million as of June 30, 2018.

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 were deemed the owner of the building during the construction period and the Company capitalized approximately $8.8 million within property and equipment and recognized a $7.3 million corresponding build-to-suit obligation in non-current liabilities in the condensed consolidated balance sheet as of June 30, 2018. Of the $8.8 million, approximately $3.5 million has been recorded as a build-to-suit asset related to construction costs incurred as of June 30, 2018.

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. 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, 2018 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.

6. 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, 2018, the total number of shares of common stock available for issuance under the 2014 Plan was approximately 2,355,000. 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, 2018, approximately 4,391,000 shares of common stock were subject to outstanding awards under the 2014 Plan.

VERSARTIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (unaudited)

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, 2018, the Company has issued approximately 224,000 shares of common stock under the ESPP.

7. 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,	
	2018	2017	2018	2017
Net loss	$(9,848)	$(36,597)	$(18,829)	$(66,319)
Weighted-average shares used to compute basic and diluted net loss per share	36,134	35,316	36,010	35,001
Basic and diluted net loss per common share	$(0.27)	$(1.04)	$(0.52)	$(1.89)

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.

8. Restructuring Plan

In October 2017, the Board of Directors of the Company approved a plan of termination to eliminate a number of positions effective October 20, 2017 (the “Restructuring Plan”), as part of its commitment to reduce costs following the failure of the Phase 3 VELOCITY trial of somavaratan to reach its primary endpoint. Simultaneously with the

Restructuring Plan the Company established a Severance Benefit Plan (the"Plan") for affected employees as well as a retention plan for retained employees. The Plan provides payment of severance benefits to affected employees of the Company.

As part of the Company's commitment to reduce operating expenses and preserve cash, the Company eliminated additional positions effective May and June 2018. The reduction included a total of 14 employees, which represented approximately 59% of its workforce as of June 26, 2018, the date affected employees were notified. Pursuant to the Plan, affected employees received certain severance benefits. For the period ended June 30, 2018, the Company incurred a one-time severance-related charge totaling approximately $3.5 million, of which $1.2 million is included within general and administrative expenses and $2.3 million is included within research and development expenses.

9. Merger & Acquisition

Pending Acquisition of Aravive Biologics, Inc.

On June 3, 2018, we entered into an Agreement and Plan of Merger and Reorganization, or the Agreement, by and among Versartis, Inc., a Delaware corporation ("Parent"), Velo Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Parent ("Merger Sub"), and Aravive Biologics, Inc., a Delaware corporation (the "Company"). Under the Agreement, Aravive will merge with a wholly owned subsidiary of Versartis in an all-stock transaction. The transaction will result in a clinical stage, Nasdaq-listed company, based in Houston, Texas, focused on the development of innovative oncology therapeutics.

VERSARTIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (unaudited)

The Agreement contains certain termination rights for us and Aravive, and further provides that, upon termination of the Agreement under certain specified circumstances, Versartis or Aravie would be obligated to pay Aravive or Versartis a termination fee of $2.5 million.

Following the proposed merger, Versartis and Aravive equity holders are each expected to own approximately 50 percent of the combined company. The transaction has been unanimously approved by the boards of directors of both companies. The transaction is expected to close during the second half of 2018, subject to approval by the stockholders of both companies and the satisfaction or waiver of other customary closing conditions.

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, 2017, included in our annual report on Form 10-K filed on March 6, 2018 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," "estimat "expect," "intend," "may," "plan," "project," "seek," "should," "strategy," "target," "will," "would" and similar expressions or 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" or "Our") has been an endocrine-focused biopharmaceutical company that was developing a novel long-acting form of recombinant human growth hormone, somavaratan (VRS-317), for growth hormone deficiency, or GHD, an orphan disease.

Somavaratan is a fusion protein consisting of rhGH and a proprietary half-life extension technology known as XTEN®. We in-licensed the rights to use 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. If we commercialize 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.

Recent Developments

In September 2017, we announced that the VELOCITY Phase 3 clinical trial of somavaratan in pediatric GHD did not meet its primary endpoint of non-inferiority. All ongoing clinical trials of somavaratan have been concluded as of the end of 2017 and the U.S. Investigational New Drug Application, or IND, and all equivalent filings in foreign countries have been withdrawn. Based on a full review of the data from the Phase 3 VELOCITY trial, feedback from the FDA during the development of somavaratan, and an objective assessment by external regulatory experts, the company

believes it could not successfully file for approval based on the existing dataset. The investment and delay in time-to-market that further development would require, significantly impact the business case for somavaratan, given the potential that one or more long-acting growth hormone products may already be commercialized for pediatric growth hormone deficiency during that time.

In October 2017, following the announcement of our failed Phase 3 VELOCITY trial to meet its primary endpoint, the board of directors approved a plan to reduce the size of our workforce by approximately 62%. The workforce reduction, which was completed in the fourth quarter of 2017, was designed to reduce our operating expenses while we conducted a review of development options for somavaratan. We incurred a one-time severance-related charge totaling approximately $3.4 million, all of which was paid in 2017, and of which $2.7 million and $0.7 million were recorded in research and development expenses and general and administrative expenses, respectively.

In October 2017, in parallel with our announcement regarding our assessment of the viability of further development of somavaratan and our restructuring plan, we announced that we engaged Cowen to assist in evaluating possible strategic transactions that could maximize our expertise and resources.

In May and June 2018, as part of our commitment to reduce costs and preserve cash, we terminated an additional number of positions to further reduce our operating expenses as we evaluated possible strategic transactions.

In June 2018, the Company entered into a merger agreement with Aravive Biologics, Inc. to form a clinical stage, Nasdaq-listed company, based in Houston, Texas, focused on the development of innovative oncology therapeutics. Aravive Biologics is a privately held clinical stage biopharmaceutical company developing novel, highly selective therapies designed to treat serious cancers and certain fibrotic diseases. Under this merger agreement, Aravive will merge with a wholly owned subsidiary of Versartis in an all-stock transaction. Following the proposed merger, Versartis and Aravive equity holders are each expected to own approximately 50 percent of the combined company. This transaction is expected to close during the second half of 2018, subject to approval by the stockholders of both companies and the satisfaction or waiver of other customary closing conditions.

Financial overview

Revenue

We have never generated net income from operations on an annual basis, and, as of June 30, 2018, we had an accumulated deficit of $393.1 million, primarily as a result of research and development and general and administrative expenses. We have never earned revenue from commercial sales of any of our product candidates. In August 2016, we entered into an exclusive license and supply agreement with Teijin, a pharmaceutical company based in Japan, pursuant to which we granted to Teijin an exclusive license to develop, use, sell, offer for sale, import, and otherwise commercialize, in Japan, any pharmaceutical product incorporating somavaratan. In exchange for such rights, we received a nonrefundable upfront payment of $40.0 million in 2016. We recognized the $40.0 million as contract revenue in Q4 2017 upon termination of the agreement in January 2018 as our obligations under the agreement were substantively complete at December 31, 2017.

In the future, we may generate revenue from a variety of sources, including product sales if we develop products which are approved for sale, license fees, milestones, research and development and royalty payments in connection with strategic collaborations or government contracts, or licenses of our intellectual property.

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.

Since the results of our Phase 3 VELOCITY trial in 2017, we have restructured our Company to reduce costs, which included a substantial reduction in our workforce.

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 decrease in future periods, reflecting our reduced headcount and infrastructure.

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, gains and losses on foreign currency exchange contracts, as well as interest charges associated with our build-to-suit lease obligation.

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 6, 2018 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, 2018, 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, 2018 and 2017

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)	
	2018	2017			2018	2017		
Operating expenses:								
Research and development	$3,438	$28,618	(25,180)	-88%	$7,038	$50,622	$(43,584)	-86%
General and administrative	6,003	7,572	(1,569)	-21%	10,920	15,228	(4,308)	-28%
Loss from operations	(9,441)	(36,190)	(26,749)	-74%	(17,958)	(65,850)	(47,892)	-73%
Interest income	249	242	7	3 %	442	441	1	-1 %
Other income (expense), net	(656)	(521)	135	26 %	(1,313)	(782)	531	68 %
Net loss before provision for income taxes	(9,848)	(36,469)	(26,621)	-73%	(18,829)	(66,191)	(47,362)	-72%
Provision for income taxes	—	128	(128)	NM	—	128	(128)	NM
Net loss	$(9,848)	$(36,597)	$(26,749)	-73%	$(18,829)	$(66,319)	$(47,490)	-72%

Research and development expense

Research and development expense decreased $25.2 million, or 88%, to $3.4 million for the three months ended June 30, 2018 from $28.6 million for the same period in 2017. For the six months ended June 30, 2018 research and development expense decreased $43.6 million or 86 %, to $7.0 million from $50.6 million for the same period in 2017. The decrease in research and development expense was primarily due to the termination of clinical and manufacturing related contracts that supported the company's Phase 3 clinical trials for somavaratan following the Phase 3 VELOCITY trial failing to meet its primary endpoint, as well as a substantial reduction in our workforce.

General and administrative expense

General and administrative expense decreased $1.6 million, or 21%, to $6.0 million for the three months ended June 30, 2018 from $7.6 million for the same period in 2017. For the six months ended June 30, 2018 general and administrative expense decreased $4.3 million or 28 %, to $10.9 million from $15.2 million for the same period in

2017.The decrease was attributable to the reduction in workforce and our continued efforts to reduce consulting and professional services expenses following the Phase 3 VELOCITY trial failing to meet its primary endpoint, partially offset by an increase in professional services attributable to our proposed merger transaction with Aravive Biologics.

Other income (expense), net

Other income (expense), increased $0.1 million to $0.6 million of other expense for the three months ended June 30, 2018 from other expense of $0.5 million for the same period in 2017. This increase was primarily due to interest charges related to our build-to-suite lease obligation.

Liquidity and capital resources

Since our inception and through June 30, 2018, 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, 2018, we had cash and cash equivalents of $67.8 million, a majority of which is invested in money market funds at several highly rated financial institutions.

While we assess and identify future opportunities to diversify our pipeline, we will need to obtain additional financing to build out our pipeline 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, such as a strategic transaction. 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 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, the requirements of which will depend on many factors, including:

- the rate of progress and cost of any future potential 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 on a larger scale;
- the costs of commercialization activities if 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 potential 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 June 30,	
	2018	2017
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$(15,296)	$(56,805)
Investing activities	1,896	(1,009)
Financing activities	35	2,399
Net increase (decrease) in cash and cash equivalents	$(13,365)	$(55,415)

Cash used in operating activities

Net cash used in operating activities was $15.3 million and $56.8 million in the six months ended June 30, 2018 and 2017, respectively. Cash used in operating activities in 2017 is primarily attributable to the use of funds in our operations related to the development of our product candidates. Cash used in operating activities in 2018 decreased compared to 2017 due to the termination of a number of supplier contracts, including commercial contracts with contract manufacturers as a result of the failure of the Phase 3 VELOCITY trial to meet its primary endpoint.

Cash used in investing activities

Net cash provided by and used in investing activities was $1.9 million and $1.0 million in the six months ended June 30, 2018 and 2017, respectively. Cash provided by investing activities in 2018, primarily relates to inducement payments received from the Landlord of our leased facility in Menlo Park, California, located at 1020 Marsh Road. Cash used in investing activities in 2017 is primarily due to a letter of credit associated with our facility at 1020 Marsh Road, for which we commenced this lease in March 2017.

Cash provided by financing activities

Net cash provided by financing activities was $.03 million and $2.4 million in the six months ended June 30, 2018 and 2017, respectively. Cash provided by financing activities consisted of proceeds from issuance of common stock in connection with employee benefit plans.

As of June 30, 2018, we had cash and cash equivalents of approximately $67.8 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 current business plan.

Contractual obligations and commitments

During the six months ended June 30, 2018, 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, 2017.

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, 2018, we had cash and cash equivalents of $67.8 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.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

An evaluation as of June 30, 2018 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer, who serves as our principal executive and 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, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer, who serves as our principal executive officer and our principal financial officer, has concluded that our disclosure controls and procedures were effective at June 30, 2018 .

Changes in Internal Control over Financial Reporting

Our management, including our Chief Executive Officer, who serves as our principal executive and financial officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2018 , 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, who serves as our principal executive and financial officer, has concluded, based on his 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 Merger between the Company and Aravie, Inc.

If the merger is not completed, we may be unsuccessful in completing an alternative transaction on terms that are as favorable as the terms of the proposed transaction with Aravive, or at all, and we may be unable to reestablish an operating business. Our board of directors may decide to pursue a dissolution and liquidation of the company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

To date, our current assets consist primarily of cash, cash equivalents and marketable securities, our listing on the Nasdaq Global Select Market and the Merger Agreement with Aravive. While we have entered into the Merger Agreement with Aravive, the closing of the merger with Aravive may be delayed or may not occur at all and there can be no assurance that the merger will deliver the anticipated benefits we expect or enhance shareholder value. If we are unable to consummate the merger with Aravive, our board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the proposed merger with Aravive. Attempting to complete an alternative transaction will be costly and time consuming, and we can make no assurances that such an alternative transaction would occur at all. Alternatively, our board of directors may elect to continue operations or decide to pursue a dissolution and liquidation of the company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of the company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable

provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include severance obligations and fees and expenses related to the merger. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of the company.

Risks related to the development and commercialization of our product candidate

We are in the process of evaluating strategic alternatives and assessing our clinical programs following the failure of the Phase 3 clinical trial for our only product candidate, somavaratan, to meet its primary endpoint.

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. In September 2017, we announced that the Phase 3 clinical trial of somavaratan failed to meet its primary endpoint. As a result, management is in the process of evaluating the Company’s future direction, including whether we will continue to seek the development, regulatory approval and commercialization of somavaratan in the future, or pursue an alternative course of action, including the possible consummation of a strategic transaction. There is no guarantee that we will be successful in any pursuit of strategic alternatives, or that any alternative course of action will lead to the success of our business. If we do continue our efforts to develop and commercialize somavaratan in the future, we may not be successful.

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. Because our Phase 3 clinical trial failed to meet its primary endpoint, we concluded all active trials of somavaratan by the end of 2017. We would need to conduct additional studies and trials in the future in order to continue to pursue regulatory approval of somavaratan in the United States. 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 do not 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 clinical trials of somavaratan were conducted and extended treatment with somavaratan results in any concerns about its safety or efficacy, we may be unable to successfully develop or commercialize somavaratan.

We may not be able to continue the development of, obtain regulatory approval for, or successfully commercialize somavaratan.

We have expended considerable resources and efforts on the development of somavaratan. The failure of our Phase 3 clinical trial to meet its primary endpoint has caused a substantial delay in our ability to commercialize somavaratan. If we continue to develop

and commercialize somavaratan, we will need to commence and complete additional clinical trials that satisfy the specified primary endpoint criteria, manage clinical and manufacturing activities, obtain necessary regulatory approvals from the FDA and comparable regulatory authorities elsewhere, and successfully market and commercialize somavaratan. The increased time required to conduct additional clinical trials and obtain regulatory approval may make it more difficult to commercialize somavaratan successfully. If we continue with the development of somavaratan, there is no guarantee that we will be able to successfully complete these steps, and if we do not continue with the development of somavaratan, then we may not be able to continue our business in its current form and will be required to pursue alternative business strategies.

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

The conduct of any future 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 successful 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 future clinical trials in a way that leads to BLA submission and approval of somavaratan. Failure to complete, or further delays in our clinical trials would prevent us from or delay us in commercializing somavaratan.

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 would also need 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 clinical trials. In October 2012, we entered into an agreement with Boehringer Ingelheim to develop a more efficient, larger-scale manufacturing process. However, this agreement was terminated in December 2017, following the announcement that our Phase 3 clinical trial failed to meet its primary endpoint. If we receive regulatory approval for somavaratan in the future, 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 intended 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. We terminated our agreement with Owen Mumford following our September 2017 announcement that our Phase 3 clinical trial failed to meet its primary endpoint. If we 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.

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. Our Phase 3 clinical trial for somavaratan failed to meet its primary endpoint, and we do not know whether we will continue to pursue the regulatory approval and commercialization of somavaratan. 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 if further clinical studies were conducted could increase our development costs and delay completion of the study.

We may not be able to initiate or resume 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. The failure of our Phase 3 clinical trial to meet its primary endpoint may make it more difficult to enroll sufficient numbers of patients if further clinical trials were conducted. 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.

If we continue to seek regulatory approval and commercialization of somavaratan, we will need to conduct additional trials and enroll patients at new clinical sites. 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 study enrollment if we conduct further trials. 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 future 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. Our Phase 3 clinical trial of somavaratan failed to meet its primary endpoint, and we would need to conduct additional clinical trials in order to continue our efforts to obtain approval of somavaratan.

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 unable to successfully complete clinical studies or other testing, if the results of such 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 decide to conduct additional clinical studies and 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 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 any future clinical trials that we may conduct, 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, and failed to meet its primary endpoint in our Phase 3 trial. If we continue with clinical development of somavaratan, 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.

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 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 further clinical trials were conducted that 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.

In September 2017, we announced that our Phase 3 clinical trial failed to meet its primary endpoint, and we do not know whether we will conduct future clinical trials to continue our efforts to obtain approval for somavaratan. If we were to conduct future clinical trials, we would anticipate seeking regulatory approval for somavaratan in the United States, Europe, Japan and Canada for treatment of pediatric GHD patients. 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 a future 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, 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.

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

In addition to any possible future efforts to commercialize 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 strategic transactions, 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.

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.

If we continue with the development of somavaratan, we will focus on developing 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. The Phase 3 clinical trial of somavaratan failed to meet its primary endpoint. 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. Although we have taken steps to reduce and control our costs following the failure of our Phase 3 clinical trial to meet its primary endpoint, we continue to incur research and development and general and administrative expenses related to our operations. In addition, we are exploring a range of alternatives to enhance stockholder value, including a potential strategic transaction, which could impact our cash needs that cannot be determined at this time. 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, 2018, we had an accumulated deficit of $393.1 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, and our Phase 3 clinical trial recently failed to meet its primary endpoint. We anticipate that our expenses will increase to the extent we:

- continue the research and development of our only product candidate, somavaratan, and any future product candidates;
- conduct additional clinical studies of somavaratan in the future;
- 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 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 any further safety studies and Phase 3, Phase 2/3, and Phase 2 clinical trials that may be conducted with 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 additional studies in the future . 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, 2018, we had approximately $67.8 million in cash and cash equivalents, which includes $59.1 million in net proceeds we received from our public offering in October and November 2016. We believe that our existing cash and cash equivalents, 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 future 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, should we elect to do so;
- 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, and the failure of our Phase 3 clinical trial to meet its primary endpoint may make it more difficult to raise funds in the future. 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 historically have relied 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 relied on ResearchPoint Global to oversee and manage our VISTA study and global Phase 3 pediatric trial of somavaratan, and we may rely on these or similar organizations in the future. 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 may 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 our product candidates. 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 have limited experience in, and we do not own facilities for, clinical-scale manufacturing of our product candidates and we historically have relied on third-party contract manufacturing organizations to manufacture and supply drug product for our clinical studies of somavaratan and our autoinjector device. 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.

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 restart and 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. For example, 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.

Following the failure of our Phase 3 clinical trial to meet its primary endpoint, Teijin notified us, pursuant to the agreement's terms, that it would be terminating the Exclusive License Supply Agreement between us and Teijin. This decision was followed by discussions between us and Teijin regarding the failure of our Phase 3 VELOCITY trial to meet its primary endpoint during which it was determined that continuing with the License Agreement was no longer in the best interests of either party. The agreement was terminated in January 2018.

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.
- 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.
- 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.
- 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. 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.
- 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, some of whom joined our company prior to May 2015, when our current chief executive officer began serving in that role. The loss of the services of any of these people or instability in our executive team, which may be more likely due to the failure of our Phase 3 clinical trial to meet its primary endpoint, 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. Following the failure of our Phase 3 clinical trial to meet its primary endpoint, key employees have left and may leave the Company, and we may not have the resources to hire, or we may choose not to replace additional personnel. 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 have implemented a series of cost-savings measures, and we do not know what the impact of those measures.

Following the failure of our Phase 3 clinical trial to meet its primary endpoint, management implemented a number of cost-savings measures, including a significant reduction in force, in order to preserve cash as the Company assesses its alternatives. We do not know what the impact of these measures will be, but the changes could divert management resources, which could adversely impact the Company’s business 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 may 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 ongoing regarding 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.

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

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), (iii) limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after 2018 and elimination of net operating loss carrybacks, (iv) one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time, and (vi) modifying or repealing many business deductions and credits. The overall impact of the tax law is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. We will continue to examine the impact the Tax Act may have on our business.

Our ability to use net operating loss carryforwards to reduce future tax payments may be subject to limitations.

We have federal and state net operating loss carryforwards that will begin to expire, if not utilized. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses may be limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We may experience ownership changes in the future and subsequent shifts in our stock ownership. As a result, we may be limited in the portion of net operating loss carryforwards that we can use in the future to offset taxable income for U.S. federal income tax purposes.

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. One of the oppositions resulted in an adverse initial decision by the European Patent Office that is currently under appeal. The patent remains 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 expired 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 additional 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, 2018 the reported sale price of our common stock has fluctuated between $1.38 and $23.46 per share. Since the announcement of the failure of our Phase 3 clinical trial to meet its primary endpoint in September 2017, our stock price has declined substantially. 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, 2018, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock, in the aggregate, beneficially owned shares representing approximately 21.9% 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, or we may fail to satisfy applicable Nasdaq listing requirements.

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, our stock price could decline, and we may be unable to maintain compliance with applicable NASDAQ listing requirements.

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

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Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation by Reference SEC Form	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
31.1*	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 8, 2018 /s/ Jay P. Shepard
Jay P. Shepard

Chief Executive Officer

(Principal Executive and Financial Officer)