

# VERSARTIS, INC.

## FORM 10-Q (Quarterly Report)

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended **June 30, 2016**

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**

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**Versartis, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**26-4106690**  
(I.R.S. Employer  
Identification Number)

**4200 Bohannon Drive, Suite 250  
Menlo Park, California 94025  
(650) 963-8580**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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 29, 2016, there were 29,541,214 outstanding shares of common stock, par value \$0.0001 per share, of Versartis, Inc.

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VERSARTIS, INC.  
QUARTERLY REPORT ON FORM 10-Q  
FOR THE QUARTERLY PERIOD ENDED June 30, 2016

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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**VERSARTIS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

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

	<u>June 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
<b>Assets</b>		
Current Assets		
Cash and cash equivalents	\$ 137,497	\$ 182,069
Prepaid expenses	5,559	2,542
Other current assets	136	—
Total current assets	<u>143,192</u>	<u>184,611</u>
Other assets	611	327
Property and equipment, net	373	389
Total assets	<u>\$ 144,176</u>	<u>\$ 185,327</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable	\$ 732	\$ 1,671
Accrued liabilities	7,703	7,156
Total liabilities	<u>8,435</u>	<u>8,827</u>
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, \$0.0001 par value, 50,000,000 shares authorized at June 30, 2016 and December 31, 2015; 29,541,214 and 29,420,247 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	3	3
Additional paid-in capital	375,729	369,933
Accumulated other comprehensive loss	(206)	—
Accumulated deficit	(239,785)	(193,436)
Total stockholders' equity	<u>135,741</u>	<u>176,500</u>
Total liabilities and stockholders' equity	<u>\$ 144,176</u>	<u>\$ 185,327</u>

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

**VERSARTIS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
*(unaudited)*  
*(in thousands, except per share data)*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
<b>Operating expenses</b>				
Research and development	\$ 16,397	\$ 11,940	\$ 34,589	\$ 29,040
General and administrative	5,909	7,556	11,823	12,737
Total operating expenses	<u>22,306</u>	<u>19,496</u>	<u>46,412</u>	<u>41,777</u>
Loss from operations	(22,306)	(19,496)	(46,412)	(41,777)
Interest income	129	65	234	114
Other income (expense), net	59	(236)	(171)	(10)
Net loss	<u>\$ (22,118)</u>	<u>\$ (19,667)</u>	<u>\$ (46,349)</u>	<u>\$ (41,673)</u>
Net loss per share - basic and diluted	<u>\$ (0.75)</u>	<u>\$ (0.67)</u>	<u>\$ (1.57)</u>	<u>\$ (1.60)</u>
Weighted-average common shares used to compute basic and diluted net loss per share	<u>29,489</u>	<u>29,293</u>	<u>29,455</u>	<u>26,035</u>

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

**VERSARTIS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
*(unaudited)*  
*(in thousands)*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss	\$ (22,118)	\$ (19,667)	\$ (46,349)	\$ (41,673)
Other comprehensive loss:				
Cumulative foreign currency translation adjustment	(10)	—	(1)	—
Unrealized loss on cash flow hedge	(258)	—	(205)	—
Comprehensive loss	<u>\$ (22,386)</u>	<u>\$ (19,667)</u>	<u>\$ (46,555)</u>	<u>\$ (41,673)</u>

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,	
	2016	2015
<b>Cash flows from operating activities</b>		
Net loss	\$ (46,349)	\$ (41,673)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	106	113
Stock-based compensation expense	5,377	6,225
Changes in assets and liabilities		
Prepaid expenses and other assets	(3,636)	(1,270)
Accounts payable	(940)	72
Accrued liabilities and other liabilities	547	312
Net cash used in operating activities	(44,895)	(36,221)
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(90)	(5)
Net cash used in investing activities	(90)	(5)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock in follow-on offering, net of issuance costs	—	80,208
Proceeds from issuance of common stock in connection with employee benefit plans	413	125
Net cash provided by financing activities	413	80,333
Net increase (decrease) in cash and cash equivalents	(44,572)	44,107
Cash and cash equivalents at beginning of period	182,069	170,566
Cash and cash equivalents at end of period	<u>\$ 137,497</u>	<u>\$ 214,673</u>

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

## VERSARTIS, INC.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS *(unaudited)*

#### **1. Formation and Business of the Company**

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

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

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

In the opinion of the Company, the accompanying unaudited condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of its financial position as of June 30, 2016, its results of operations for the three- and six-months ended June 30, 2016, and 2015, comprehensive loss for the three- and six-months ended June 30, 2016 and 2015, and cash flows for the six months ended June 30, 2016, and 2015. The December 31, 2015 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, 2015 included in the Company’s annual report on Form 10-K filed on March 8, 2016 with the U.S. Securities and Exchange Commission (“SEC”).

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

##### ***Basis of Presentation and Use of Estimates***

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

The accompanying condensed consolidated financial position as of June 30, 2016 and as of December 31, 2015, results of operations and statements of comprehensive loss for the three- and six-months ended June 30, 2016 and 2015, and cash flows for the six months ended June 30, 2016 and 2015 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 of the Company's consolidated operations, with the exception of Versartis GmbH, which utilizes the euro.

As of June 30, 2016, the Company had cash and cash equivalents balance of \$137.5 million consisting of cash and investments in highly liquid U.S. money market funds. The Company believes that its existing cash and cash equivalents will be sufficient to sustain operations for at least the next 12 months based on its existing business plan. If the Company’s potential Phase 3 clinical trials are successful, it will need to raise additional capital in order to further advance its product candidates towards regulatory approval and potential commercialization. Since inception, the Company has incurred net losses and negative cash flows from operations. At June 30, 2016, the Company had an accumulated deficit of \$239.8 million and working capital of \$134.8 million. The Company expects to continue to incur losses from costs related to the continuation of research and development and administrative activities for the foreseeable future. Although management has been successful in raising capital in the past, most recently in January 2015, 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.

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

**Segments**

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

**Concentration of credit risk**

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

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

**Derivative Financial Instruments**

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

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

**Risk and Uncertainties**

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

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

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to launch and commercialize any product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be at terms acceptable by the Company.

**Cash and Cash Equivalents**

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. At June 30, 2016 and December 31, 2015 the Company's cash and cash equivalents were held in multiple institutions in the United States and Europe and include deposits in money market funds which were unrestricted as to withdrawal or use.

**Property and Equipment, Net**

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

***Impairment of Long-Lived Assets***

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by the comparison of the carrying amount to the undiscounted future net cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value (i.e. determined through estimating projected discounted future net cash flows or other acceptable methods of determining fair value) arising from the asset. There have been no such impairments of long-lived assets as of June 30, 2016 or December 31, 2015.

***Fair Value of Financial Instruments***

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

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

- Level I Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level II Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level III Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

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

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

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

***Preclinical and Clinical Trial Accruals***

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

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

***Research and Development***

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

***Income Taxes***

The Company accounts for income taxes under the asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted

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

tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

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

**Stock-Based Compensation**

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

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
<b>Operating Expenses</b>				
Research and development	\$ 1,020	\$ 632	\$ 1,604	\$ 1,236
General and administrative	1,995	3,605	3,773	4,989
Total	\$ 3,015	\$ 4,237	\$ 5,377	\$ 6,225

**Comprehensive Loss**

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

**Net Loss per Share of Common Stock**

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, stock options, restricted stock units and shares issued under our Employee Stock Purchase Plan are considered to be potentially dilutive securities. Because the Company has reported a net loss for all of the periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

**Recent Accounting Pronouncements**

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

VERSARTIS, INC.

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

In March 2016, the FASB issued Accounting Standards Update (“ASU”) No. 2016-09, Compensation – Stock Compensation (Topic 718) (“ASU 2016-09”), which simplified certain aspects of the accounting for share-based payment transactions, including income taxes, classification of awards and classification in the statement of cash flows. ASU 2016-09 will be effective for the Company beginning in its first quarter of 2018. 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 February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU is a comprehensive new leases standard that amends various aspects of existing guidance for leases and requires additional disclosures about leasing arrangements. The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements.

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

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes, which requires all deferred income tax assets and liabilities to be classified as noncurrent on the balance sheet. The new standard is effective for annual reporting periods beginning after December 15, 2016 with early adoption permitted. The Company is currently evaluating the impact of adoption and will apply the guidance and disclosure provisions of the new standard upon adoption.

In August 2014, the FASB issued new guidance related to the disclosures around going concern. The new standard provides guidance around management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The Company will apply the guidance and disclosure provisions of the new standard upon adoption in its first quarter of 2017. The Company is currently evaluating the impact of the adoption of this guidance on its consolidated financial condition, results of operations and cash flows.

**3. Balance Sheet Components**

*Prepaid expenses (in thousands)*

	June 30, 2016	December 31, 2015
Preclinical and clinical (1)	\$ 4,837	\$ 1,770
Other	722	772
<b>Total</b>	<b>\$ 5,559</b>	<b>\$ 2,542</b>

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

*Accrued Liabilities (in thousands)*

	June 30, 2016	December 31, 2015
Payroll and related	\$ 2,192	\$ 2,296
Preclinical and clinical	5,010	4,376
Professional services	358	69
Other	143	415
<b>Total</b>	<b>\$ 7,703</b>	<b>\$ 7,156</b>

VERSARTIS, INC.

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

4. Fair Value Measurements

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, 2016 (unaudited)			
	Total	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market funds	\$ 126,924	\$ 126,924	\$ —	\$ —
Foreign currency derivative contracts	135	—	135	—
	<u>\$ 127,195</u>	<u>\$ 127,059</u>	<u>\$ 135</u>	<u>\$ —</u>
	Fair Value Measurements at December 31, 2015			
	Total	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market funds	\$ 132,647	\$ 132,647	\$ —	\$ —
Foreign currency derivative contracts	—	—	—	—
	<u>\$ 132,647</u>	<u>\$ 132,647</u>	<u>\$ —</u>	<u>\$ —</u>

5. Derivative Financial Instruments

The Company's operations in foreign countries expose it to market risk associated with foreign currency exchange rate fluctuations between the U.S. dollar and various foreign currencies, the most significant of which is the Euro. In order to manage this risk, the Company hedges a portion of its foreign currency exposures related to certain forecasted operating expenses using foreign currency exchange forward or option contracts. In general, the market risk related to these contracts is offset by corresponding gains and losses on the hedged transactions. By working only with major financial institutions and closely monitoring current market conditions, the Company seeks to limit its counterparty risk to these contracts. Therefore, the Company's overall risk of loss in the event of a counterparty default is exposed to the currency risk. The Company does not enter into derivative contracts for trading or speculative purposes.

The Company hedges its exposure to foreign currency exchange rate fluctuations for forecasted operating expenses that are denominated in a non-functional currency. The derivative instruments the Company uses to hedge this exposure are designated as cash flow hedges and have maturity dates of 12 months or less. Upon executing a hedging contract and quarterly thereafter, the Company assesses both retrospective and prospective hedge effectiveness using regression analysis to assert the hedge is highly effective at offsetting changes in cash flow. The Company includes time value in its effectiveness assessment and recognizes any ineffectiveness in other income (expense). The effective component of the Company's hedge is recorded in accumulated other comprehensive income (OCI) within stockholders' equity and subsequently reclassified into earnings when the hedged exposure affects earnings. Derivatives not designated as hedges are not speculative and are used to manage the Company's economic exposure to foreign exchange rate movements but do not meet the strict hedge accounting requirements. Changes in the fair value of derivatives not designated in hedging relationships are recorded directly in earnings. Substantially all of the gains and losses related to the hedged forecasted transaction reported in accumulated other comprehensive income at June 30, 2016 are expected to be reclassified to research and development expenses within the next 12 months.

The cash flow effects of the Company's derivative contracts for the six months ended June 30, 2016 are included within net cash provided by operating activities in the condensed consolidated statements of cash flows.

The Company had notional amounts outstanding on foreign currency exchange contracts of 9.1 million euros (a purchased call option on the Euro) at June 30, 2016 and none outstanding at December 31, 2015.

While all of the Company's derivative contracts allow it the right to offset assets or liabilities, the Company has presented amounts on a gross basis. Under the International Swap Dealers Association, Inc. master agreements with the respective counterparties of the foreign currency exchange contracts, subject to applicable requirements, the Company is allowed to net settle transactions of the same currency with a single net amount payable by one party to the other. The Company does not have any credit contingent features associated with its derivatives.

VERSARTIS, INC.

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

The following table summarizes the classification and fair value s of derivative instruments on the Company's condensed consolidated balance sheets included within other current assets at June 30, 2016 (none outstanding at December 31, 2015) (in thousands):

	June 30, 2016			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	\$ 135	Other accrued liabilities	\$ —
Total derivatives		<u>\$ 135</u>		<u>\$ —</u>

The following table summarizes the effect of our foreign currency exchange contracts on the Company's condensed consolidated financial statements (in thousands):

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Derivatives designated as hedges:			—	
Gains (losses) recognized in accumulated OCI (effective portion)	\$ (203)	\$ —	\$ (151)	\$ —
Gains (losses) reclassified from accumulated OCI into operating expenses (effective portion)	\$ 54	\$ —	\$ 54	\$ —
Gains (losses) recognized in other income (expense), net (ineffective portion and amounts excluded from effectiveness testing)	\$ —	\$ —	\$ —	\$ —
Derivatives not designated as hedges:				
Gains (losses) recognized in other income (expense), net	\$ (48)	\$ —	\$ (48)	\$ —

From time to time, the Company may discontinue cash flow hedges and as a result, record related amounts in other income (expense), net on its condensed consolidated statements of operations. The Company did not record any amounts in other income (expense), net for the three months ended June 30, 2016 as a result of the discontinuance of cash flow hedges.

As of June 30, 2016, the Company held one derivative contract related to a foreign currency exchange contract (a purchased call option on the Euro) and the derivative was in an asset position at the end of the period.

## 6. Commitments and Contingencies

### Facility Leases

In March 2014, the Company entered into an operating facility lease agreement to lease 12,943 square feet in Menlo Park, California for its new headquarters building for a period of thirty-nine months. The total obligation for the Company under this lease is approximately \$0.9 million as of June 30, 2016.

In December 2015, the Company entered into an operating sublease agreement to lease 10,891 square feet of additional office space in Menlo Park for a period of twenty-four months. The sublease date began January 1, 2016 and the total obligation under this sublease for the Company is approximately \$0.8 million as of June 30, 2016.

***Supplier Agreement***

In May 2016, the Company entered into a Manufacture and Supply Agreement with Owen Mumford Limited, a leading medical device manufacturer, pursuant to which the Company engaged Owen Mumford to: (1) manufacture a proprietary disposable auto-injector device and (2) assemble and supply a final combination product including the device and somavaratan (VRS-317), its proprietary long-acting form of human growth hormone. The Company will supply somavaratan in prefilled syringes to Owen Mumford for incorporation into the final combination product.

Under the agreement, Owen Mumford agrees to manufacture the auto-injector device used in the product exclusively for the Company in the field of human growth hormone deficiency treatment, subject to a minimum purchase obligation. The Company is required to purchase its entire requirement of the final combination product from Owen Mumford, except that after a specified time period after regulatory approval in the European Union (“EU”), the Company may purchase from third parties a portion of its requirement for the European Economic Area. In addition, after a specified time period after regulatory approval in any major jurisdiction, the Company is required to purchase from Owen Mumford a minimum quantity of the product in each year. If the Company does not purchase such minimum quantity, it may pay a shortfall payment to Owen Mumford to maintain the scope of its exclusivity. If the Company fails to purchase the minimum and decline to pay the shortfall payment, the exclusivity will be limited to long-acting human growth hormone products. The agreement also includes customary terms and conditions relating to forecast, ordering, delivery, inspection and acceptance, among other matters.

The initial term of the agreement continues until ten (10) years after the Company’s acceptance of the first shipment of the final combination product, and may be renewed for an additional time period by mutual agreement of the parties. The agreement may be earlier terminated by either party for the other party’s uncured material breach or insolvency. In addition, either party may terminate the agreement without cause upon twelve (12) months advance notice. If terminated by Owen Mumford without cause, Owen Mumford must continue to supply the auto-injector device and assemble the final combination product until the Company is able to identify, appoint, and qualify through all necessary regulatory approvals an alternate manufacturer.

**7. Stockholders’ Equity*****Equity Incentive Plans***

The Company’s Board of Directors, or Board, and stockholders previously approved the 2014 Equity Incentive Plan, or the 2014 Plan, which became effective on March 21, 2014. As of June 30, 2016, the total number of shares of common stock available for issuance under the 2014 Plan was approximately 1,161,000. 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, 2016, approximately 4,937,000 shares of common stock were subject to outstanding awards under the 2014 Plan.

In March 2014, the Board and stockholders approved the 2014 Employee Stock Purchase Plan, or the ESPP, which became effective as of March 5, 2014. The Company initially reserved a total of 150,000 shares of common stock for issuance under the ESPP. Unless the Board provides otherwise, beginning on January 1, 2015, and continuing until the expiration of the ESPP, the total number of shares of common stock available for issuance under the ESPP will automatically increase annually on January 1 by the lesser of (i) 1% of the total number of issued and outstanding shares of common stock as of December 31 of the immediately preceding year, or (ii) 300,000 shares of common stock. As of June 30, 2016, the Company has issued approximately 109,000 shares of common stock under the ESPP.

VERSARTIS, INC.

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

**Accumulated Other Comprehensive Loss**

The following table summarizes the changes in accumulated other comprehensive loss by component (in thousands):

	Foreign Currency Items	Unrealized Gains and Losses on Cash Flow Hedges	Total
Balance at December 31, 2015	\$ —	\$ —	\$ —
Other comprehensive loss before reclassifications	(1)	(151)	(152)
Amounts reclassified from accumulated other comprehensive loss	—	(54)	(54)
Net current period other comprehensive loss	(1)	(205)	(206)
Balance at June 30, 2016	\$ (1)	\$ (205)	\$ (206)

Amounts reclassified for gains (losses) on cash flow hedges are recorded as part of net loss on our condensed consolidated statements of operations.

**8. Net loss per share of Common Stock**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss	\$ (22,118)	\$ (19,667)	\$ (46,349)	\$ (41,673)
Weighted-average shares used to compute basic and diluted net loss per share	29,489	29,293	29,455	26,035
Basic and diluted net loss per common share	\$ (0.75)	\$ (0.67)	\$ (1.57)	\$ (1.60)

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

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

	June 30,	
	2016	2015
Options to purchase common stock	4,403,810	3,234,916
Restricted stock units	532,835	280,255

## 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, 2015, included in our annual report on Form 10-K filed on March 8, 2016 with the U.S. Securities and Exchange Commission (SEC).*

### Special note regarding forward-looking statements

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

### Overview

Versartis, Inc. (the "Company" "We" "Our") is an endocrine-focused biopharmaceutical company initially developing a novel long-acting form of recombinant human growth hormone, somavaratan (VRS-317), for growth hormone deficiency, or GHD, an orphan disease. A key limitation to current recombinant human growth hormone, or rhGH, products is that they impose the burden of daily injections over multiple years, often resulting in poor adherence, which in turn can lead to suboptimal treatment outcomes in GHD patients. Despite this limitation, global annual sales from currently marketed rhGH products have grown to more than \$3 billion in 2014. Based on market research, we believe that the market for rhGH products can continue to grow up to \$4 billion following the launch of long-acting rhGH therapies. Somavaratan is intended to reduce the burden of daily treatment by requiring significantly fewer dosing events and injections, potentially improving adherence and, therefore, treatment outcomes. Accordingly, we believe somavaratan may take significant market share. Our first indication for somavaratan is pediatric GHD, which represents an approximately \$1.5 billion existing market opportunity. We have completed the Phase 2a stage of our pediatric GHD clinical trial, and have analyzed two year safety, efficacy and adherence data from our ongoing Extension Study. We have received feedback from various authorities, including the Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, providing guidance on the design of our Phase 3 clinical trial. In early 2015, we initiated a pediatric GHD Phase 3 registration trial, which we refer to as the VELOCITY trial. We have been enrolling participants into the VELOCITY trial at U.S., Canadian and European sites and we continue to administer somavaratan to patients enrolled in our ongoing Extension Study. We expect to complete enrollment of the VELOCITY trial by mid-August 2016. We received feedback from the Japanese regulatory agency, Pharmaceuticals Medicines and Devices Agency, or the PMDA, on our pediatric GHD Phase 2/3 registration trial in Japan. We submitted to the PMDA the agreed upon protocol for the pediatric GHD Phase 2/3 trial, received a completed Clinical Trial Notification, or CTN, and initiated the Phase 2/3 trial in April 2015. In the first half of 2015, we received feedback from the FDA and the EMA on our development plan in adult GHD and as a result we are conducting a Phase 2 trial prior to a potential Phase 3 for this population. We initiated the Phase 2 trial, which we refer to as the VITAL trial, in September 2015 and enrollment is complete. We have since initiated an Extension study to the VITAL trial where we will be transitioning patients from monthly to twice-monthly dosing. We may develop somavaratan for additional growth disorders, such as idiopathic short stature, or ISS, small for gestational age, or SGA, and Turner Syndrome, which together accounted for approximately 20% of the global rhGH market in 2014. We have global rights to somavaratan and, if somavaratan is approved, given the highly concentrated prescriber base, we intend to commercialize it with our own specialty sales force in North America, and potentially other geographies.

Somavaratan is a fusion protein consisting of rhGH and a proprietary half-life extension technology known as XTEN<sup>®</sup>, which we in-licensed from Amunix Operating, Inc., or Amunix. Amunix has granted us an exclusive license under its patents and know-how related to the XTEN technology to develop and commercialize up to four licensed products, including somavaratan. Once we start commercializing a licensed product, we will owe to Amunix a royalty on net sales of the licensed products until the later of the expiration of all licensed patents or ten years from the first commercial sale in the relevant country. The royalty payable is one percent of net sales for the first two marketed products, but higher single-digit royalties are payable if we market additional products, or if we substitute one marketed product for another. If we elect to substitute one marketed product for another, in addition to royalties, we would also be required to make milestone and other payments totaling up to \$40 million per marketed product.

## **Financial overview**

### ***Summary***

We have never generated net income from operations, and, at June 30, 2016, we had an accumulated deficit of \$239.8 million, primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments and research and development payments in connection with potential future strategic partnerships, we have not yet generated any revenue. Somavaratan is at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to incur significant and increasing losses from operations for the foreseeable future as we seek to advance somavaratan through its on-going and planned Phase 2 and 3 clinical trials, and there can be no assurance that we will ever generate significant revenue or profits.

### ***Research and development expenses***

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

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

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

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

### ***General and administrative expenses***

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

### ***Other income (expense), net***

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

## **Critical accounting policies, significant judgments and use of estimates**

Our management's discussion and analysis of financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, ("U.S. GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed consolidated financial statements and in Note 2 to our audited consolidated financial statements contained in the Annual Report on Form 10-K filed on March 8, 2016 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, 2016, 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, 2016 and 2015

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)	
	2016	2015			2016	2015		
Operating expenses:								
Research and development	\$ 16,397	\$ 11,940	\$ 4,457	37%	\$ 34,589	\$ 29,040	\$ 5,549	19%
General and administrative	5,909	7,556	(1,647)	-22%	11,823	12,737	(914)	-7%
Loss from operations	(22,306)	(19,496)	2,810	14%	(46,412)	(41,777)	4,635	11%
Interest income	129	65	64	98%	234	114	120	105%
Other income (expense), net	59	(236)	295	-125%	(171)	(10)	(161)	NM (1)
Net loss	<u>\$ (22,118)</u>	<u>\$ (19,667)</u>	<u>\$ 2,451</u>	12%	<u>\$ (46,349)</u>	<u>\$ (41,673)</u>	<u>\$ 4,676</u>	11%

(1) Not Meaningful

#### Research and development expense

Research and development expense increased \$4.5 million, or 37%, to \$16.4 million for the three months ended June 30, 2016 from \$11.9 million for the same period in 2015. For the six months ended June 30, 2016, research and development expense increased \$5.5 million, or 19%, to \$34.5 million from \$29.0 million for the same period in 2015. The increase in research and development expense was primarily due to a \$2.9 million increase for the three months ended June 30, 2016 and a \$4.2 million increase for the six months ended June 30, 2016 related to clinical costs to support our ongoing global VELOCITY pediatric trial, VITAL Phase 2 trial for adults and our Phase 2/3 trial of somavaratan in pediatric patients in Japan. For the three months ended June 30, 2016 and 2015, substantially all of our research and development expense related to our somavaratan drug development activity.

#### General and administrative expense

General and administrative expense decreased \$1.6 million, or 22%, to \$5.9 million for the three months ended June 30, 2016 from \$7.5 million for the same period in 2015. For the six months ended June 30, 2016, general and administrative expense decreased \$0.9 million, or 7%, to \$11.8 million from \$12.7 million for the same period in 2015. The decrease in G&A expenses was primarily due to a one-time non-recurring expense of \$2.4 million associated with our CEO transition in May 2015, partially offset by additional fees related to consulting and professional services to support our continued growth.

#### Other income (expense), net

Other income (expense), net increased \$0.2 million to \$0.2 million of other expense for the six months ended June 30, 2016 from other expense of zero for the same period in 2015. This increase was primarily due to gains from foreign currency transactions offset by minimal losses related to our foreign currency exchange contracts.

## Liquidity and capital resources

Since our inception, we have financed our operations through private placements of our equity securities, debt financing and, more recently, our initial public offering in 2014 and our secondary offering in January 2015. At June 30, 2016, we had cash and cash equivalents of \$137.5 million, a majority of which is invested in money market funds at several highly rated financial institutions. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of somavaratan and any additional product candidates. Specifically, we have incurred substantial expenses in connection with our VELOCITY trial and we expect to continue to incur substantial expenses in connection with our Extension Studies the VITAL trial, and additional Phase 2 and 3 clinical trials that we have initiated or plan to conduct.

If our ongoing Phase 2 and Phase 3 clinical trials for somavaratan are successful, we will continue to require additional financing to further develop our product candidates and fund operations for the foreseeable future and we will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the rate of progress and cost of our clinical studies;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;

- the cost of preparing to manufacture somavaratan on a larger scale;
- the costs of commercialization activities if somavaratan or any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements; and
- the emergence of competing technologies or other adverse market developments.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

### **Cash flows**

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

	Six Months Ended June 30,	
	2016	2015
(In thousands)		
Net cash (used in) provided by:		
Operating activities	\$ (44,895)	\$ (36,221)
Investing activities	(90)	(5)
Financing Activities	413	80,333
Net increase (decrease) in cash and cash equivalents	<u>\$ (44,572)</u>	<u>\$ 44,107</u>

#### *Cash used in operating activities*

Net cash used in operating activities was \$44.9 million and \$36.2 million in the six months ended June 30, 2016 and 2015, respectively, which was primarily due to the use of funds in our operations related to the development of our product candidates. Cash used in operating activities in 2016 increased compared to 2015 primarily due to a higher net loss from operations as we continued to increase our research and development expenditures to develop somavaratan related to our manufacturing and clinical costs and expand our general and administrative functions to support continued growth.

#### *Cash used in investing activities*

Cash used in investing activities consisted primarily of investment in furniture, equipment and leasehold improvements made for additional office space in Menlo Park, California, which commenced in January 2016.

#### *Cash provided by financing activities*

Net cash provided by financing activities was immaterial in the six months ended June 30, 2016, compared to \$80.3 million in the same period of 2015. Cash provided by financing activities for 2016 and 2015 consisted of net proceeds from the exercise of employee stock options in 2016 and primarily of the proceeds from our follow-on offering in 2015.

As of June 30, 2016, we had cash and cash equivalents of approximately \$137.5 million. 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. If our potential Phase 3 clinical trials are successful, we will need to raise additional capital in order to further advance our product candidates towards regulatory approval and potential commercialization.

### **Contractual obligations and commitments**

During the six months ended June 30, 2016, 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, 2015, except for a manufacturing and supply agreement entered in May 2016 described below:

In May 2016, we entered into a Manufacture and Supply Agreement with Owen Mumford Limited, a leading medical device manufacturer, pursuant to which we engaged Owen Mumford to: (1) manufacture a proprietary disposable auto-injector device and (2) assemble and supply a final combination product including the device and somavaratan (VRS-317), our proprietary long-acting form of human growth hormone. We will supply somavaratan in prefilled syringes to Owen Mumford for incorporation into the final combination product.

Under the agreement, Owen Mumford agrees to manufacture the auto-injector device used in the product exclusively for us in the field of human growth hormone deficiency treatment, subject to a minimum purchase obligation. We are required to purchase our entire requirement of the final combination product from Owen Mumford, except that after a specified time period after regulatory approval in the European Union (“EU”), we may purchase from third parties a portion of our requirement for the European Economic Area. In addition, after a specified time period after regulatory approval in any major jurisdiction, we are required to purchase from Owen Mumford a minimum quantity of the product in each year. If we do not purchase such minimum quantity, we may pay a shortfall payment to Owen Mumford to maintain the scope of our exclusivity. If we fail to purchase the minimum and decline to pay the shortfall payment, the exclusivity will be limited to long-acting human growth hormone products. The agreement also includes customary terms and conditions relating to forecast, ordering, delivery, inspection and acceptance, among other matters.

The initial term of the agreement continues until ten (10) years after our acceptance of the first shipment of the final combination product, and may be renewed for an additional time period by mutual agreement of the parties. The agreement may be earlier terminated by either party for the other party’s uncured material breach or insolvency. In addition, either party may terminate the agreement without cause upon twelve (12) months advance notice. If terminated by Owen Mumford without cause, Owen Mumford must continue to supply the auto-injector device and assemble the final combination product until we are able to identify, appoint, and qualify through all necessary regulatory approvals an alternate manufacturer.

#### ***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.

#### ***JOBS Act accounting election***

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

### **Item 3. Quantitative and qualitative disclosures about 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, 2016, we had cash and cash equivalents of \$137.5 million consisting of cash and investments in highly liquid U.S. money market funds. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are substantially all short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

#### ***Foreign Currency Market Risk***

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

### **Item 4. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

An evaluation as of June 30, 2016 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our “disclosure controls and procedures.” Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the “Exchange Act,” defines “disclosure controls and procedures” as controls and other procedures of a company that are designed to ensure that the information required to be disclosed by

a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at June 30, 2016.

#### **Changes in Internal Control over Financial Reporting**

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2016, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Limitations on the Effectiveness of Controls**

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

## PART II: OTHER INFORMATION

### Item 1. Legal proceedings

We are not currently subject to any material legal proceedings.

### Item 1A. Risk Factors.

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

#### **Risks related to the development and commercialization of our product candidate**

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

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

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

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

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

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

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

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

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

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

***Because the results of preclinical testing and earlier clinical trials and the results to date in our Extension Study are not necessarily predictive of future results, somavaratan may not have favorable results in later clinical trials or receive regulatory approval.***

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

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

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

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

Although we have completed the Phase 2a stage of a Phase 1b/2a clinical trial of somavaratan, the conduct of our Phase 3 clinical trial and the submission of a successful Biologics License Application, or BLA, is a complicated process. As an organization, we have never conducted a Phase 3 clinical trial, have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted a BLA before. Consequently, even though the Phase 2a stage of our Phase 1b/2a clinical trial was successful, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA submission and approval of somavaratan. Failure to complete, or delays in our clinical trials would prevent us from or delay us in commercializing somavaratan.

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

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

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

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

For example, we enrolled 48 patients in the United States over approximately eight months in the Phase 1b stage of our Phase 1b/2a clinical trial of somavaratan. The last patient was enrolled in the Phase 2a stage of the trial in November 2013, and the trial was completed by mid-2014. As the outcome of the Phase 2a stage of the trial was successful, we initiated a Phase 3 clinical trial in the United States, Western Europe and Canada in early 2015. As we expect to study only pre-pubertal naïve to treatment subjects in the Phase 3 clinical trial, we will need to seek participation of additional patients in that trial. We will need to activate new clinical sites and enroll patients at forecasted rates at both new and existing clinical sites. Our forecasts regarding the rates of clinical site activation and patient enrollment at those sites are based on a number of assumptions, including assumptions based on past experience with the Phase 1b stage of the Phase 1b/2a clinical trial. However, there can be no assurance that those forecasts will be accurate or that we will not face delays in our Phase 3 clinical trial. As with all global clinical trials, enrollment in our Phase 3 clinical trial is dependent on obtaining clearance from regulatory authorities in each country in which it 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 prior to enrollment or during the conduct of the study, the Phase 3 trial may be delayed.

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

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

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

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

- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate or patients may drop out of these clinical studies at a higher rate than we anticipate;
- the cost of clinical studies or the manufacturing of our product candidates may be greater than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies of our product candidates for various reasons, including a finding that our product candidates have unanticipated serious side effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;
- regulators may not approve our proposed clinical development plans;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical studies of our product candidates may be insufficient or inadequate.

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

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

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

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

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

Our product candidate, somavaratan, has not completed clinical development. The risk of failure of clinical development is high. It is impossible to predict when or if this 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 other comparable foreign regulatory authority.

Pediatric subjects taking somavaratan have reported adverse events, such as mild and transient injection site pain and erythema. Other adverse events that have occurred in >5% of pediatric subjects to date include headache and extremity pain. No serious side effects have been reported to date. However, we cannot provide assurance that side effects from somavaratan in current or future clinical trials will continue to be mild 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 comparable foreign regulatory authorities could order us to cease further development of 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 comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

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

Assuming the success of our clinical trials, we anticipate seeking regulatory approval for somavaratan in the United States, Europe and Canada for treatment of pediatric GHD patients based on a twice-monthly dosing regimen. It is possible that the FDA, the EMA, the PMDA or Health Canada may not consider the results of our clinical trials to be sufficient for approval of somavaratan for this indication. In general, the FDA suggests that sponsors complete two adequate and well-controlled clinical studies to demonstrate

effectiveness because a conclusion based on two persuasive studies will be more compelling than a conclusion based on a single study. Even if we achieve favorable results in our Phase 3 clinical trial, and considering that somavaratan is a new molecular entity, the FDA may nonetheless require that we conduct additional clinical studies, possibly using a different clinical study design.

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

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

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

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

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

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

***Somavaratan has never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. In addition, to successfully commercialize somavaratan, we must also design, manufacture, and gain regulatory approval of a delivery device to safely, effectively, and conveniently administer somavaratan in relevant patient types.***

Somavaratan has never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale 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, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Somavaratan is a biological molecule, or biologic, rather than a small molecule chemical compound, and as a result we face special uncertainties and risks associated with scaling up manufacturing. The manufacture of biologics involves complex processes, including developing cells or cell systems to produce the biologic, growing large quantities of such cells and harvesting and purifying the biologic produced by them. As a result, the cost to manufacture biologics is generally far higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is difficult to reproduce. Somavaratan was previously produced for us by a third-party contract manufacturer using a small-scale process that was too expensive and inefficient to support the dosages necessary for our ongoing and planned clinical trials. In October 2012, we entered into an agreement with Boehringer Ingelheim to develop a more efficient, larger-scale manufacturing process. However, scaling up and improving a biologic

manufacturing process is a difficult and uncertain task, and we can give no assurance that we will be successful in developing and implementing this new process. Additionally, if we receive regulatory approval for somavaratan, in order to successfully commercialize somavaratan, we will need to manufacture quantities of somavaratan using commercially viable processes at a scale sufficient to meet anticipated demand. Even if we are able to do so, if the therapeutically effective dosage of somavaratan is higher than we anticipate or the obtainable sales price is lower than we anticipate, we may not be able to successfully commercialize somavaratan.

To commercialize somavaratan, we must design, manufacture, and gain regulatory approval of a delivery device to safely, effectively and conveniently administer somavaratan. We have engaged third-party manufacturers to design a suitable prototype for commercial purposes. There can be no assurance that these efforts will be successful. If we are unsuccessful in developing a suitable delivery device, our commercialization efforts would be impaired, which could have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

We currently hold \$10.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

## **Risks related to our financial condition and need for additional capital**

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We do not have any products approved for sale, and to date we have focused principally on developing our only product candidate, somavaratan. Evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or approved products on the market. We continue to incur significant research and development and general and administrative expenses related to our operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. We have incurred significant operating losses in each year since our inception and expect to incur substantial and increasing losses for the foreseeable future. As of June 30, 2016, we had an accumulated deficit of \$239.8 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 a follow-on offering of our common stock in January 2015. We have devoted substantially all of our efforts to research and development, including clinical studies, but have not completed development of any product candidate. We anticipate that our expenses will increase substantially as we:

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

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

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

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

- complete development activities, including our ongoing Extension Studies and Phase 3, Phase 2/3, and Phase 2 clinical trials of somavaratan, successfully and on a timely basis;
- demonstrate the safety and efficacy of somavaratan to the satisfaction of the FDA and obtain regulatory approval for somavaratan and future product candidates, if any, for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;

- set a commercially viable price for our products;
- establish and maintain supply and manufacturing relationships with reliable third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop a commercial organization capable of sales, marketing and distribution of any products for which we obtain marketing approval in markets where we intend to commercialize independently;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- achieve market acceptance of our products, if any;
- establish, maintain and protect our intellectual property rights and avoid third-party patent interference or patent infringement claims; and
- attract, hire and retain qualified personnel.

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

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

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

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any 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 product 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, 2016, we had approximately \$137.5 million in cash and cash equivalents. 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 clinical studies;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the cost of preparing to manufacture somavaratan on a larger scale;
- the costs of commercialization activities if somavaratan or any future product candidate is approved, including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of any products launched by us or future partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
- the emergence of competing technologies or other adverse market developments; and
- the costs of attracting, hiring and retaining qualified personnel.

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

we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies or research and development programs or our commercialization efforts.

### **Risks related to our reliance on third parties**

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

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

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

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

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

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

Our product candidate, somavaratan, is a biologic and therefore requires a complex production process. In October, 2012, we transferred production of somavaratan to Boehringer Ingelheim. In connection with the transfer of production, we made certain changes to the manufacturing process in order to increase its scale and efficiency. We cannot assure that the FDA and the EMA will

agree to the changes in the manufacturing process to support commercialization. In addition, current agreements with our manufacturer do not provide for the entire supply of the drug product necessary for full scale commercialization. If we and our manufacturer cannot agree to the terms and conditions necessary for our commercial supply needs, or if our manufacturer terminates the agreement in response to a material breach by us or otherwise becomes unable to fulfill its supply obligations, we would not be able to manufacture somavaratan until a qualified alternative manufacturer is identified, which could also delay the development of, and impair our ability to commercialize, somavaratan.

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

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

***Any future collaboration agreements we may enter into for somavaratan or any other product candidate may place the development 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 may enter into additional collaboration agreements with third parties with respect to somavaratan for the commercialization of this candidate outside the United States, or with respect to future product candidates for commercialization in or outside the United States. Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to any such collaborations;
- 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 due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- 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 could 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;
- 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;
- 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; and
- 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.

Any termination or disruption of collaborations could result in delays in the development of product candidates, increases in our costs to develop the product candidates or the termination of development of a product candidate.

#### **Risks related to the operation of our business**

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

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

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

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

As of July 31, 2016, we had 51 employees. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

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

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

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

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and

exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) December 31, 2019, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least \$1.0 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 \$1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

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

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

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

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

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

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

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

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

#### **Risks related to intellectual property**

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

We are a party to intellectual property license agreements with third parties, including with respect to somavaratan, and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we may not be able to develop and market any product that is covered by these agreements. For example, we license substantially all of the intellectual property relating to somavaratan from Amunix, and the loss of our license agreement with Amunix would therefore materially adversely affect our ability to proceed with any development or potential commercialization of our product candidates as currently planned. Amunix has the right to terminate the license upon 30 days' written notice with respect to a particular target and the related products if (i) during any consecutive 18 month period our cumulative funding of research, development and commercialization activities in respect of such target is not at least \$250,000, in which case we would have the right to extend the applicable 18 month period by paying Amunix \$150,000; or (ii) if we do not use commercially reasonable measures to develop and commercialize licensed products based on such target. Termination of this license, or reduction or elimination of our licensed rights under it or any other license, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business and financial condition.

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

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

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

We license substantially all of the intellectual property relating to somavaratan from Amunix. We do not presently own any issued patents or pending patent applications, and our license agreement with Amunix provides that inventions relating to somavaratan are owned by Amunix. We are therefore dependent on Amunix to apply for, prosecute, maintain, defend and, in some cases, enforce the patent rights necessary to conduct our business. However, we cannot be certain this will be done in a manner consistent with the best interests of our business. The process of applying for patents is expensive and time-consuming, and Amunix may not, or may not be able to, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or Amunix will fail to identify patentable aspects of our respective research and development output before it is too late to obtain patent protection. While Amunix has obtained a number of patents relating to the XTEN technology, and applied for a number of other patents relating to the XTEN technology in general, and somavaratan in particular, we cannot assure you that the pending 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 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 licensors 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 preliminary finding by the European Patent Office that is currently under appeal. The patent remains in effect until complete adjudication of the appeal, which is a multi-year process. An adverse final determination in any such proceeding could reduce the

scope of, or invalidate, 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 these 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 our patented technology and products, 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 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 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 licensor does 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 licensor may not be granted patent term extension either in the United States or in any foreign country because of, for example, we or our licensors failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing 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.

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

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

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

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

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

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

In 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

pending 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 29, 2016 the reported sale price of our common stock has fluctuated between \$6.41 and \$23.46 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price for our common stock may be influenced by many factors, including the following:

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

- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- the other risks described in this “Risk factors” section.

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

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

As of July 31, 2016, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock, in the aggregate, beneficially own shares representing approximately 76% 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 newly public company, and our management devotes substantial time to new compliance initiatives.***

As a newly public company, we are incurring 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. The expenses required in order to adequately prepare for being a public company have been and will be material, and 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, beginning with our annual report on Form 10-K for the fiscal year ended December 31, 2015. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

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

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

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

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

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

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

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

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

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

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

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

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

- our board of directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our stockholders are not able to act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock are not able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors, the chairman of the board, the chief executive officer or the president;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors are able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

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

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

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

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

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

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

None

**Item 6. Exhibits**

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporation by Reference</u>			
		<u>Form</u>	<u>SEC File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>
3.1	Amended and Restated Certificate of Incorporation of Versartis, Inc.	8-K	001-36361	3.1	03/26/2014
3.2	Amended and Restated Bylaws of Versartis, Inc.	S-1/A	333-193997	3.4	03/06/2014
4.1	Form of Stock Certificate	10-Q	001-36361	4.1	05/14/2014
10.1*	Owen Mumford Manufacturing Supplier Agreement				
31.1*	Certification required by Rule 13a-14(a) or Rule 15d-14(a).				
31.2*	Certification required by Rule 13a-14(a) or Rule 15d-14(a).				
32.1*+	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

\* Filed Herewith.

+ 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 2, 2016

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

Date: August 2, 2016

/s/ Joshua T. Brumm  
\_\_\_\_\_  
Joshua T. Brumm  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

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

24 May 2016

(1) OWEN MUMFORD LIMITED

and

(2) VERSARTIS GMBH

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MANUFACTURING AND SUPPLY AGREEMENT

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**THIS AGREEMENT** is made on the 24<sup>th</sup> day of May 2016 (the "**Agreement**")

**BETWEEN**

- (1) **OWEN MUMFORD LIMITED**, a company incorporated in England and Wales with registration number 1257871 whose registered office address is at Brook Hill, Woodstock, Oxford OX20 1TU, UK ("**Owen Mumford**"); and
- (2) **VERSARTIS GMBH**, a limited liability company registered in Switzerland whose principal place of business is at Mühlenberg 7, 4052 Basel, Switzerland (the "**Customer**").

**BACKGROUND**

- (A) Owen Mumford is a world leader in the development and manufacture of medical devices for, amongst other things, drug delivery.
- (B) The Customer is a subsidiary of Versartis, Inc., a pharmaceutical company developing drug products including a long-acting form of recombinant human growth hormone.
- (C) The Customer wishes to appoint and Owen Mumford wishes to accept the appointment from the Customer to manufacture and supply drug delivery devices and units of combination product containing such device and drug supplied by Customer for the Customer on the terms of this Agreement.
- (D) The Customer will supply to Owen Mumford the active pharmaceutical ingredient in prefilled syringes and certain other materials which will be incorporated by Owen Mumford into the drug delivery device as set out in this Agreement.

**OPERATIVE PROVISIONS**

**1 Definitions**

1.1 In this Agreement the following words and expressions have the meaning set out below:

- Affiliate** means any company or other entity which directly or indirectly controls, is controlled by or is under common control with a party, where 'control' means the ownership of more than 50% of the issued share capital or other equity interest or the legal power to direct or cause the direction of the general management and policies of that party or such company or other entity;
- Authorised Sub-contractor** means any sub-contractor for the supply of the Device or Final Combination Product on a temporary basis under clause 4.3, as agreed between the parties from or alternatively as listed in the Quality Agreement;
- Business Days** means Monday to Friday (inclusive) except bank or public holidays in England and in the United States of America;

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

<b>Certificate of Analysis</b>	means a listing of all results for tests conducted on samples of a lot of the Device or the Final Combination Product compared to the specifications defined by the Customer and listed in the regulatory applications;
<b>Certificate of Conformity</b>	means a signed certificate issued by Owen Mumford certifying the conformity of a batch of Devices with the Specification and GMP (but excluding certification of any testing or inspection of the Drug or its syringe beyond visual inspection for damage or discoloration);
<b>Confidential Information</b>	means, in relation to each party, (i) all information in any form or medium disclosed by that party (the " <b>disclosing party</b> ") to the other party (the " <b>receiving party</b> ") under or in connection with this Agreement whether before, on or after the Effective Date, and (ii) the terms of this Agreement;
<b>Customer Materials</b>	means all materials (including the Drug) supplied by the Customer to Owen Mumford;
<b>Device</b>	means the auto-injector device as described in Part 1 of Schedule 1, or any similar auto-injector device incorporating design features within the scope of the patents or other intellectual property covering the combination of features described in Part 1 of Schedule 1, in each case solely for use in the Field;
<b>Drug</b>	means the long-acting form of human growth hormone known as somavaratan (or VRS-317);
<b>Effective Date</b>	means the date set out at the top of this Agreement;
<b>Exchange Rate</b>	means the Bank of England's published mid-market exchange rate of UK Pounds Sterling to U.S. Dollars;
<b>Exchange Rate Comparison Date</b>	means whichever is the later of the Effective Date or the latest date on which any amendment of the Price was effected under clause 10.5;
<b>Field</b>	means treatment of human growth hormone deficiency and any other condition for which any human growth hormone product is approved in the Territory, including but not limited to idiopathic short stature (ISS), small for gestational age (SGA), Prader-Willi syndrome (PWS), and Turner syndrome using any human growth hormone product or analogue;

<b>Final Combination Product</b>	means the product produced by Owen Mumford using the Device and Customer Materials (including the Drug) as described in Part 3 of Schedule 1 and as labelled and packaged in accordance with Part 2 of Schedule 1 (and for the avoidance of doubt for the purposes of the purchase commitment in clause 2.3 a Final Combination product shall include any product comprising a Device and a Drug);
<b>GMP</b>	means the principles of good manufacturing practice as set out in EC Directive 93/42/EEC, EC Directive 2003/94 and/or CRF title 21 part 210, 211 and 820 each as amended from time to time, or any successors to them and any other applicable regulations;
<b>Intellectual Property Rights</b>	means patent applications, patents, rights to inventions, copyright and related rights, trademarks, trade names and domain names, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;
<b>Limited Field</b>	means the treatment of human growth hormone deficiency and all other analogous conditions using a long-acting human growth hormone or analogous product dosed once weekly or less frequently;
<b>Minimum Order Quantity</b>	means [*] units of the Final Combination Product;
<b>Price</b>	means the fee payable by the Customer in relation to the supply of each unit of the Final Combination Product to the Customer as set out in Schedule 2;
<b>Primary Packaging</b>	means packaging that envelops the Final Combination Product and retains such Final Combination Product as described in Part 2 of Schedule 1;
<b>Purchase Order</b>	means a written order for Final Combination Product received by Owen Mumford from the Customer;

<b>Quality Agreement</b>	means a quality agreement setting out the quality standards applicable to the Device and the assembly of the Final Combination Product as agreed by the parties in accordance with clause 2.6;
<b>Secondary Packaging</b>	means any packaging which is external to the Primary Packaging as described in Part 2 of Schedule 1;
<b>Specifications</b>	means the detailed technical and other requirements for the Device and the assembly of the Final Combination Product as set out in the Quality Agreement (but excluding any specifications relating to the efficacy, chemical composition, or any other quality of the Drug);
<b>Term</b>	means the term of this Agreement as determined in accordance with clause 15; and
<b>Territory</b>	means worldwide.

1.2 In this Agreement:

1.2.1 references to clauses are to the clauses of this Agreement;

1.2.2 references to the parties are to the parties to this Agreement;

1.2.3 headings are used for convenience only and do not affect its interpretation; and

1.2.4 references to a statutory provision include references to the statutory provision as modified or re-enacted or both from time to time and to any subordinate legislation made under the statutory provision.

**2 Supply of the Device and Assembly of the Final Combination Product**

2.1 During the Term of this Agreement:

2.1.1 Owen Mumford agrees to manufacture the Device, to assemble the Device with the Customer Materials and to supply the Final Combination Product to the Customer each in accordance with the Specifications.

2.1.2 If following marketing authorisation Customer wishes to substantially modify the Device or create an alternate somavaratan device for a specific formulation, indication, geography, or other purpose, the Parties shall discuss in good faith a modification of this Agreement necessary to effectuate supply by Owen Mumford of such next generation device.

2.2 Subject to the minimum purchase obligations described in clause 4.4, Owen Mumford agrees to manufacture the Device exclusively for the Customer for use in the Field and undertakes not to manufacture the Device for any other customer for use in the Field for the Term.

2.3 The Customer agrees to purchase from Owen Mumford:

2.3.1 the Customer's entire requirement for the Final Combination Product in respect of territories and countries outside the European Economic Area during the entirety of the Term; and

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

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- 2.3.2 the Customer's entire requirement for the Final Combination Product with respect to those countries in the Territory within the European Economic Area (" **EEA Countries** "), with effect from the date of grant of the first marketing authorisation granted for the Final Combination Product in the European Union (the "**Authorisation Date**" ) and thereafter for the remainder of the Term except on the [\*] anniversary of the Authorisation Date the Customer's exclusivity commitment will be reduced to a commitment to purchase [\*] of its entire requirement for the Final Combination Product from Owen Mumford with respect to the EEA Countries. The parties may agree to extend the period of exclusivity for the EEA Countries for an additional period, by mutual written consent, subject to compliance with applicable laws.
- 2.4 Owen Mumford agrees to supply the Final Combination Product with the Primary and Secondary Packaging and any labelling, leaflets and/or trademarks specified in Part 2 of Schedule 1, or such other Primary and Secondary Packaging and labelling, leaflets and/or trademarks as are agreed in writing between the parties from time to time.
- 2.5 During the Term the Customer will provide Owen Mumford with Customer Materials in bulk packaging as required for the production of the Final Combination Product.
- 2.6 As soon as possible following signature of this Agreement, but in no event more than six (6) months after the Effective Date, the parties will prepare and negotiate in good faith a quality agreement setting out the design history file contents, Specifications, and quality standards which will apply to the Device and the Final Combination Product and such agreement shall, when executed by both parties, be annexed to Part 4 of Schedule 1 and shall form part of this Agreement (the "**Quality Agreement** "). In the event of any conflict between this Agreement and the Quality Agreement, the prevailing document shall be determined as follows:
- 2.6.1 for any conflicts related to quality assurance matters or the regulatory obligations of the parties, or any Specifications, the Quality Agreement shall prevail; and
- 2.6.2 for all other conflicts, this Agreement shall prevail.
- 2.7 Prior to delivery of the Final Combination Product to the Customer, Owen Mumford will perform design control tests (including such tests as agreed in writing between the parties) to verify that the Final Combination Product complies with the Specifications. Owen Mumford will supply a Certificate of Conformity with each batch of Final Combination Product. Owen Mumford shall send, or cause to be sent, as applicable, such certificates to the Customer prior to the shipment of the Final Combination Product. Owen Mumford shall provide the Customer, upon the Customer's written request, with copies of executed batch records, quality reports of control and test materials, deviation reports, investigation reports, and performance testing results or other documentation or materials as reasonably requested by the Customer.
- 2.8 Owen Mumford warrants that the Final Combination Product will be manufactured in accordance with GMP, applicable laws and regulations and the Quality Agreement and will comply with the Specifications on delivery. Owen Mumford shall promptly inform the Customer in writing of any proposed process changes, change to any of the agreed upon Specifications, quality standards or any

applicable laws and regulations and shall obtain the Customer's prior agreement in writing before making any such change.

- 2.9 The Customer shall inform Owen Mumford in writing at as early as stage as possible of any proposed changes to any of the Customer Materials (including without limitation any change to their specifications, design or composition) or and change of applicable laws and regulations relating to the Customer Materials, and the parties shall thereafter discuss in good faith how best to accommodate such change (including without limitation by varying this Agreement or any relevant Specifications).
- 2.10 Owen Mumford agrees to comply with any reasonable instructions provided by the Customer (to the extent they are consistent with the Quality Agreement) in relation to the incorporation of any Customer Materials into the Final Combination Product and in relation to the Primary and Secondary Packaging and inclusion or affixation of any labelling, leaflets and/or trademarks in or to the Final Combination Product as specified in Part 2 of Schedule 1.
- 2.11 Owen Mumford shall store the Customer Materials, any raw materials components or ingredients used in the production of the Final Combination Product and the Devices in accordance with the Specifications and all applicable laws and regulations for no additional charge and shall supply details of such storage to the Customer upon written request. For a period of up to [\*] following the date of issue of the Certificate of Conformity pursuant to clause 2.7, Owen Mumford will store the Final Combination Product in accordance with the Specifications and all applicable laws and regulations until they are shipped to the Customer or a third party identified by the Customer. Owen Mumford shall have no obligation to store Final Combination Product beyond such [\*] period and may thereafter at its option ship, store, or engage a third party to store such Final Combination Product at the Customer's risk and cost.
- 2.12 Owen Mumford may sub-contract its obligations under this Agreement to suppliers on the list of approved suppliers relating to the supply of the Final Combination Product under this Agreement maintained by Owen Mumford, as amended by Owen Mumford from time to time (the " **List** "), provided that:
- 2.12.1 Owen Mumford shall perform final assembly of the Device itself and shall not sub-contract final assembly other than to Authorised Sub-contractors in the limited circumstances described in clause 4.3;
- 2.12.2 Owen Mumford shall provide the List to Customer within two (2) weeks following the Effective Date and shall notify Customer of any new approved suppliers added to the List within two (2) weeks of their addition; and
- 2.12.3 Owen Mumford shall oblige each subcontractor to comply with the relevant provisions of this Agreement and remains liable to the Customer for the performance of its obligations under this Agreement, whether or not sub-contracted.

### **3 Obligations of the Customer and Owen Mumford**

- 3.1 The Customer will co-operate with Owen Mumford as may reasonably be requested by Owen Mumford relating to the manufacture of the Devices and the assembly and supply of Final Combination Product and will respond in a timely manner to all reasonable requests for information from Owen Mumford.

- 3.2 Owen Mumford will, following the receipt of a forecast from the Customer as set out in clause 4 , or as otherwise needed at a later date , provide the Customer with a written order for Customer Materials.
- 3.3 The Customer will supply, or procure the supply to Owen Mumford of all Customer Materials as may be reasonably required by Owen Mumford together with material safety data sheets and any other information reasonably necessary to ensure safe storage and handling of them by Owen Mumford. The Customer shall, or Customer's designated representative shall, deliver the Customer Materials to Owen Mumford Delivered At Place (INCOTERMS 2010) at Chipping Norton, UK. Owen Mumford agrees to only use the Customer Materials as required for the manufacture of the Devices and the assembly and supply of the Final Combination Product to the Customer in accordance with the terms of this Agreement and agrees not to:
- 3.3.1 use the Customer Materials for any commercial purpose except for the manufacture of the Devices and the assembly and supply of the Final Combination Product; or
  - 3.3.2 not to distribute any of the Customer Materials to any third party other than an Affiliate or sub-contractor of Owen Mumford as necessary for the performance of this Agreement.
- 3.4 The Customer shall provide Customer Materials to Owen Mumford as are necessary for the manufacture of the Devices and the assembly of the Final Combination Product in accordance with this Agreement. Owen Mumford understands and acknowledges that the Customer Materials: may have hazardous properties and must be handled and used with due care in accordance with the instructions provided by the Customer, taking into account the potentially hazardous nature of the Customer Materials and any procedures notified to Owen Mumford by the Customer (which may be changed by the Customer from time to time following reasonable notice to Owen Mumford) and in accordance with all applicable laws and safety regulations.
- 3.5 All Customer Materials are stored at Customer's risk, and the Customer is responsible for insuring against all loss or damage to the Customer Materials while in Owen Mumford's possession. If Customer Materials are damaged in storage, Owen Mumford shall inform the Customer of such damage as soon as reasonably possible and in no event later than forty-eight (48) hours from the time such damage is discovered by Owen Mumford. Following such notification the parties will discuss the replacement of the damaged Customer Materials and any delays to delivery of the Final Combination Product as set out in clause 4.3.
- 3.6 Owen Mumford will, on termination or expiry of this Agreement, provide notice to the Customer of any Customer Materials remaining in its possession or under its control. Customer may instruct Owen Mumford whether to return such Customer Material to the Customer or to destroy it, at the Customer's cost, except if the Agreement is terminated for Owen Mumford's breach then it shall be at Owen Mumford's cost. If the Customer does not provide instructions to Owen Mumford within thirty (30) days of receipt of written notice from Owen Mumford requesting instructions, Owen Mumford may dispose of the excess Customer Materials without any further liability or obligation to the Customer.

#### 4 **Forecasting and Purchase Orders**

- 4.1 No later than sixty (60) days from the Effective Date, and thereafter not less than sixty (60) days before the commencement of each calendar quarter, the

Customer shall provide Owen Mumford with a written non-binding forecast for the subsequent [\*] specifying the Customer's anticipated requirement for the Final Combination Product. The first [\*] of any such forecast shall represent the binding quantities of the Final Combination Product which the Customer will purchase.

- 4.2 The Customer shall supply a Purchase Order to Owen Mumford containing the following information (a) number of units of Final Combination Product required; (b) requested delivery date (such date to be not less than [\*] from date of Purchase Order); and (c) any carriage instructions or requirements. Owen Mumford reserves the right to refuse to accept any Purchase Order which is not in compliance with this clause. Owen Mumford shall acknowledge receipt and acceptance of a Purchase Order to the Customer together with information on the anticipated delivery date for Final Combination Product. Once a Purchase Order, which is compliant with the requirements of this clause 4.2, is received by Owen Mumford in accordance with the binding forecast provided by the Customer as set out in clause 4.1, Owen Mumford shall be obliged to accept such Purchase Order to manufacture and supply the Final Combination Product to the Customer. Subject to the provisions of this clause 4.2, Owen Mumford agrees to supply Final Combination Product within the requested delivery dates set out in any Purchase Order (provided that Owen Mumford shall not be in breach of this obligation if it supplies the Final Combination Product within [\*] before or after the applicable delivery date). If the aggregate Purchase Orders issued by Customer in any [\*] period exceed the binding forecast for such period, Owen Mumford shall make good faith efforts to fulfil such Purchase Orders or the portion thereof it may reasonably supply. Owen Mumford shall not be obliged to accept any conditional Purchase Orders.
- 4.3 If Owen Mumford anticipates that it will not be able to manufacture and/or supply the total ordered quantities of the Final Combination Product in accordance with the [\*] forecasts provided by the Customer in accordance with clause 4.1 and/or the Purchase Orders placed by the Customer, it shall immediately notify the Customer in writing as soon as it becomes aware of such likely inability to deliver or delay. Owen Mumford shall provide the Customer with details of the problem including an estimate of the likely delivery date and shall use its best endeavours to minimise the delay. Owen Mumford will prepare and implement a contingency plan which will include a proposal setting out how it intends to minimise the delay. If Owen Mumford is unable to manufacture and/or supply Final Combination Product to the Customer for a continuous period of more than [\*], the parties shall cooperate to enable manufacture of the Devices and/or assembly and supply of Final Combination Product by an Authorised Sub-contractor approved by the Customer. If required by the Customer, Owen Mumford will supply to such Authorised Sub-contractor any necessary documentation required to manufacture and supply Final Combination Product. The Authorised Sub-contractor shall only be used by the Customer during the period in which Owen Mumford is unable to continue to manufacture the Device and/or assemble and supply Final Combination Product. Owen Mumford shall, to the extent practicable, at the request of the Customer, source from Authorised Sub-contractors, the quantities of Final Combination Product required to satisfy the Purchase Orders placed by the Customer. If Owen Mumford is unable to manufacture and/or supply the Final Combination Product and/or is unable to source the required volume of Final Combination Product from Authorised Sub-contractors for a continuous period of more than [\*], the Customer may terminate this agreement in accordance with clause 15.2.
- 4.4 There shall be no minimum purchase requirement from the Effective Date until the [\*] anniversary of the first marketing authorisation granted for the Final

Combination Product in the United States or the European Union . Beginning in the [\*] period following the [\*] anniversary of such first marketing authorisation and thereafter during each period [\*] following the anniversary of such date , the Customer must purchase not less than the Minimum Order Quantity of the Final Combination Product in order to maintain exclusive rights to the Device in the Field . The Minimum Order Quantity shall be reduced by agreement of the parties to take account of any unanticipated circumstances which arise that may impact the Customer 's ability to purchase the Minimum Order Quantity including any delay in or failure by Owen Mumford to deliver the Final Combination Product , any Force Majeure Event ( as defined in clause 16 ) and failure to timely receive regulatory approval in any country in the Territory , any safety concerns or any restrictions on labelling or any restrictions imposed on the sale of the Final Combination Product by regulatory authorities .

4.5 If in any relevant [\*] period as defined in clause 4.4 the Customer does not purchase quantities of Final Combination Product equal to the Minimum Order Quantity, then the Customer may, at its sole option, elect to pay to Owen Mumford an amount (the "**Order Shortfall Payment**" ) calculated as follows:

[\*]

4.6 If:

4.6.1 the Customer has not purchased the Minimum Order Quantity of Final Combination Product in any applicable [\*] period as defined in clause 4.5 and has not made an Order Shortfall Payment to Owen Mumford in accordance with clause 4.5; or

4.6.2 no marketing authorisation has been granted in relation to the Final Combination Product in either the U.S. or Europe by the [\*] anniversary of the Effective Date,

each occurrence of the term "Field" herein (other than in clauses 1.1 and 11.1) shall be substituted by the term "Limited Field" each as defined in clause 1.1. Following such substitution, the exclusivity obligations in clause 2.2 and the license grant in clause 11.5 shall be restricted to the Limited Field.

4.7 The Final Combination Product will be delivered Ex Works (INCOTERMS 2010) Owen Mumford Limited, Chipping Norton, Oxfordshire, UK provided that Owen Mumford will, if requested to do so by the Customer, arrange for carriage of the Final Combination Product to the Customer's nominated address at the Customer's expense. Any carriage arranged by Owen Mumford will be at the risk of the Customer. Risk in the shipment will pass to the Customer upon delivery to the carrier at Owen Mumford's premises in Chipping Norton, UK. The Customer shall acknowledge receipt of delivery of each shipment of Final Combination Product as soon as reasonably possible following delivery to the Customer's premises.

## 5 **Inspection of Final Combination Product**

5.1 Following receipt of a shipment of the Final Combination Product from Owen Mumford, the Customer or its designated agent shall, within [\*], carry out an inspection (as defined below) of such shipment to ensure that the Final Combination Product does not have apparent defects and is accompanied by an associated Certificate of Conformity. If such Final Combination Product shows apparent defects and/or does not meet the Specifications the Customer shall promptly notify Owen Mumford in writing that it rejects the shipment setting out

reasonable details of the defect . Subject to the provisions of clause 5.3 , if the Customer does not notify Owen Mumford of rejection of such shipment within such [\*] period , such shipment of the Final Combination Product shall be deemed to have been accepted by the Customer and not to have apparent defects.

5.2 For the purposes of this Agreement, "inspection" shall mean:

- 5.2.1 comparing the applicable Purchase Order against the documentation accompanying the shipment to verify that the delivery date, identity, quantity and exterior shipment labelling comply with the Purchase Order;
- 5.2.2 verifying that the Certificate of Conformity and Certificate of Analysis for the shipment states that the Final Combination Product conforms in all material respects to the applicable Specifications; and
- 5.2.3 visually inspecting the exterior of the shipment of the Final Combination Product to verify that the shipment appears to be in good condition.

5.3 Notwithstanding the foregoing, Owen Mumford shall remain liable to the Customer, to the extent provided in clauses 5.4 or 5.5 as appropriate, for any latent defect in the Final Combination Product that subsequently is discovered which renders the relevant Final Combination Product unusable or unsaleable, if such defect could not reasonably have been discovered by inspection, is due to the failure of the Final Combination Product to meet the Specification at the time of delivery and/or is because the Final Combination Product has a latent defect and provided that the Customer informs Owen Mumford by notice in writing of such defect and rejection of the relevant shipment not later than [\*] from the date of the Customer's or its Affiliates' knowledge of such latent defect. For the purposes of this clause 5.3, a latent defect shall be any failure to meet the Specification that exists at the time of delivery and only manifests itself at a later date.

5.4 Within [\*] of receipt by Owen Mumford of a notice of rejection from the Customer in accordance with clause 5.1 or clause 5.3, Owen Mumford shall indicate in writing to the Customer whether Owen Mumford is issuing a return authorisation. In the event that a return authorisation is issued by Owen Mumford the Customer shall either destroy or return to Owen Mumford as stated in the return authorisation the quantities of the Final Combination Product in question and Owen Mumford shall replace such quantities within [\*], in either case at Owen Mumford's expense (provided that [\*] any Customer Materials necessary for the replacement of such Final Combination Product at its own expense unless [\*]). [\*] replacement of Customer Materials shall [\*]. If the payment in respect of such quantities of the Final Combination Product is outstanding, it shall be postponed until such replacement quantities of the Final Combination Product are received and accepted by the Customer in accordance with this clause 5.

5.5 After receipt of any rejection notice from the Customer pursuant to clause 5.1 or clause 5.3, if Owen Mumford does not issue a return authorisation under clause 5.4, and if the relevant defect relates to non-compliance with the Specification, Owen Mumford shall evaluate a retained sample of any batch of the Final Combination Product rejected by the Customer for non-conformity with the Specifications within [\*] of receipt of such notice, and shall present its findings with respect to the Final Combination Product to the Customer. If such tests confirm non-conformity with the Specification, Owen Mumford shall promptly supply to the Customer (at Owen Mumford's cost and expense) a conforming batch in the same quantity as the rejected batch and shall reimburse the Customer for any out of pocket costs or expenses reasonably incurred by the

Customer including shipping charges or the cost of destruction (as Owen Mumford elects) in relation to such non-conforming batch (provided that [\*] any Customer Materials necessary for the replacement of such Final Combination Product at its own expense unless [\*]). [\*] r replacement of Customer Materials shall [\*]. If the parties cannot agree on whether the batch of the Final Combination Product in question conforms to the Specifications, an independent qualified laboratory reasonably acceptable to both parties, and at a cost to be borne by the party found to be in error, shall evaluate both the Customer's and Owen Mumford's samples of the Final Combination Product from the batch in question, and the definitive results of such laboratory shall be final and binding on the parties. If the batch of the Final Combination Product in question is determined to be non-conforming, such non-conforming batch shall be held for Owen Mumford's disposition, or shall be returned to Owen Mumford, as directed by Owen Mumford no later than [\*] following such determination, in each case at Owen Mumford's expense. Owen Mumford shall replace each non-conforming batch of the Final Combination Product, or the non-conforming portion thereof, with conforming Final Combination Product within [\*] (provided that [\*] any Customer Materials necessary for the replacement of such Final Combination Product at its own expense unless [\*]). [\*] replacement of Customer Materials shall [\*]. If the batch of the Final Combination Product in question is determined to be conforming and provided that the Certificate of Conformity did not indicate it to be non-conforming, such batch of the Final Combination Product shall be returned to the Customer at the Customer's cost and expense.

- 5.6 If Owen Mumford's performance of its obligations under this Agreement is prevented or delayed by any breach of clauses 2, 4 or 5 as a result of any action or omission by the Customer, Owen Mumford will not be liable to the extent that any costs, charges or losses sustained or incurred by the Customer arose from such breach or act or omission of the Customer. For the avoidance of doubt, any defect in the Final Combination Product (whether pursuant to clause 5.1 or 5.3) caused solely by the Customer Materials shall be the responsibility of the Customer and shall not be subject to clauses 5.4 or 5.5. Where a defect in the Final Combination Product is caused solely by the Customer Materials, if requested by the Customer, Owen Mumford shall provide reasonable assistance to the Customer to promptly replace the defective Final Combination Product at the Customer's expense.
- 5.7 Provided that Owen Mumford complies with its obligations under clause 5.4 and 5.5 in relation to any rejected or non-conforming Final Combination Product [\*] in relation to any defect or non-conformity in such Final Combination Product.

## **6 Stock**

- 6.1 Owen Mumford shall maintain (or have immediately available by way of consignment) stocks of all raw materials, components and ingredients used in the production of the Final Combination Product (except Customer Materials) as required to ensure that it will be able to produce the Final Combination Product as required by the Customer in accordance with the [\*] forecasts provided by the Customer in accordance with clause 4.1 and Owen Mumford shall ensure that it has placed sufficient orders for Customer Materials as required in accordance with clause 3.2.
- 6.2 Owen Mumford will not keep or supply any Final Combination Product that has less than [\*] of its shelf life remaining as at the time of delivery to the Customer. Any out of date or damaged Final Combination Product will be immediately destroyed by Owen Mumford at its cost in accordance with applicable law and such destruction shall be fully documented.

## **7 Amendments to the Specifications**

- 7.1 Amendments to the Device, the Final Combination Product and/or Specifications may only be made with the written agreement of both parties in accordance with this clause 7. Where such changes are required to comply with any legal and/or regulatory requirements, the parties shall use reasonable endeavours to agree any changes to the Device, Final Combination Product and/or Specifications (and any cost impact resulting from such changes). Where agreement cannot be reached as to the changes required and terms applicable to such changes the Customer shall be entitled to terminate this Agreement, subject to payment of the Price for all Final Combination Product supplied or ordered prior to the date of termination.
- 7.2 Owen Mumford must notify the Customer at least [\*] prior to making any change to the Specifications and/or validated processes or procedures for moulding, assembly, packaging, quality control and quality assurance operations related to the manufacturing of Final Combination Product or any services provided under this Agreement including reasonable details of the changes it is proposing to make.
- 7.3 The Customer understands and accepts that changes to the Device, the Final Combination Product and/or Specifications may impact on regulatory or other approvals obtained by Owen Mumford and that as a result additional development work may be required to be undertaken. Any such development work shall be undertaken on terms (including as to cost) to be agreed between the parties provided that any changes required as a result of changes proposed by Owen Mumford shall be at Owen Mumford's cost.
- 7.4 Any changes may also impact on the Price payable by the Customer and any changes to the Device, Final Combination Product and/or Specifications are subject to agreement as to the Price applicable to such modified Final Combination Product.
- 7.5 If any changes or amendments are agreed to by the parties in accordance with this clause 7, the parties will promptly confirm in writing any update to Schedules 1 and/or 2 and the relevant party will implement any changes or amendments accordingly.

## **8 Regulatory Approvals and Compliance**

- 8.1 Owen Mumford will be responsible, at its cost, for preparing and maintaining all approvals and registrations of manufacturing facilities and quality assurance systems required for the manufacture of Devices and the assembly and supply of the Final Combination Product under this Agreement.
- 8.2 The Customer shall use reasonable efforts to advise Owen Mumford in a timely fashion of any regulatory submissions relating to the Final Combination Product which may result in inquiries from the regulatory authorities requiring responses from Owen Mumford. Owen Mumford shall use reasonable efforts to promptly respond to any such inquiries and provide all information requested by such regulatory authorities, which shall be within: (i) [\*] from Owen Mumford's receipt of the inquiry; or (ii) the timeframe set forth by such regulatory authorities, whichever is shorter.

- 8.3 Owen Mumford will be responsible, at its sole cost, for preparing and maintaining the technical file for the Device and the Final Combination Product and will provide the technical file to the Customer for the purpose of assisting the Customer to obtain regulatory approvals for the Device and the Final Combination Product in accordance with clause 8.4 . Owen Mumford shall return any original documents held by it on the Customer's behalf to the Customer promptly following expiry or termination of this Agreement and shall destroy any copies , unless the Customer requests Owen Mumford provide them to the Customer at the Customer's sole cost.
- 8.4 The Customer will be responsible for obtaining and maintaining all necessary regulatory approvals and registrations for the use of the Final Combination Product in conjunction only with the Drug in its own name in each country in which it intends to use or sell the Final Combination Product.
- 8.5 Owen Mumford will maintain, in sufficient detail and in accordance with GMP, comprehensive, accurate and up to date validation documents and production records relating to the manufacture of the Device and the assembly of the Final Combination Product and will provide copies of these to the Customer on request.
- 8.6 Owen Mumford will ensure that it, and any sub-contractor conducting any of the manufacture and supply, has in place (and maintains during the period that it is conducting any manufacture or supply) all approvals, permits and licences relating to the premises where any of the manufacture and/or supply is taking place as are required for the manufacture of the Device and/or the assembly of the Final Combination Product intended for use in the administration of human medicinal products.

## **9 Audit**

- 9.1 Owen Mumford will permit the Customer, its representatives and any regulatory authorities to:
- 9.1.1 inspect Owen Mumford's work under this Agreement and its manufacturing facilities;
  - 9.1.2 inspect all relevant records of Owen Mumford relating to the manufacture of the Devices and/or the assembly and supply of the Final Combination Product; and
  - 9.1.3 access relevant representatives of Owen Mumford.

Such inspections by the Customer or its representatives will take place during regular business hours and require reasonable prior notice to Owen Mumford and may take place no more than [\*] during the Term with the exception of audits or inspections required by regulatory authorities, in response to or following a recall as set out in clause 14 or a prior audit at which issues were identified. The Customer will provide Owen Mumford with the identity of its representatives in advance and Owen Mumford will accept such representatives unless it has objectively valid reasons for not doing so.

- 9.2 Owen Mumford shall promptly notify, consult and keep the Customer informed of any inquiries, inspections and/or legal actions by any regulatory authority relating to the manufacture of the Devices or assembly of Final Combination Product at any of Owen Mumford's facilities. The Customer shall have the right to participate in any inspection by any regulatory authority involving Final Combination Product,

but only in consultation with and after consent of Owen Mumford, such consent not to be unreasonably withheld, delayed or conditioned.

- 9.3 Owen Mumford shall provide the Customer, promptly after receipt by Owen Mumford, with a summary of any inspection reports and/or legal actions with or by any regulatory authority relating to the manufacture of Devices or assembly of Final Combination Product.
- 9.4 In connection with any pre-approval inspections by any regulatory authority of Owen Mumford's facilities where manufacturing, storage or testing of Devices or Final Combination Product or their components takes place, Owen Mumford shall permit appropriate Customer personnel to be present during such inspection and shall provide the Customer with timely communication and updates on pre-approval inspections by any regulatory authority for the Devices or Final Combination Product. In addition, Owen Mumford shall keep the Customer timely and reasonably informed on an on-going basis as to any proposed responses regarding corrective or remedial actions to be taken as a result of any such pre-approval inspection, including, without limitation, any corrective or remedial action relating to Owen Mumford's facilities or any third party's facilities used for the benefit of Owen Mumford.
- 9.5 The rights of access and information granted under this clause 9 will be without prejudice to the obligations of confidentiality contained elsewhere in this Agreement.

## **10 Payment**

- 10.1 In consideration of the supply of the Final Combination Product in accordance with this Agreement by Owen Mumford, Owen Mumford will be entitled to invoice the Customer for the Price. Owen Mumford shall be entitled to invoice the Price following delivery of the Final Combination Product to the Customer in accordance with clause 4.
- 10.2 Owen Mumford will send all invoices to the invoice address as specified in Schedule 2. Invoices shall be due for payment within [\*] of date of receipt of the invoice. Invoices shall be paid by telegraphic transfer unless otherwise agreed by Owen Mumford in writing.
- 10.3 The Customer will pay each invoice in U.S Dollars to the bank account specified in Schedule 2 or as is otherwise nominated in writing on the relevant invoice or by Owen Mumford from time to time.
- 10.4 If at any time the Exchange Rate deviates from the Exchange Rate as at the Exchange Rate Comparison Date by [\*] or more in either direction for a continuous period of [\*] or more, then either party may so notify the other, specifying:
- 10.4.1 the Exchange Rate as at the Exchange Rate Comparison Date;
  - 10.4.2 the average Exchange Rate during the relevant [\*] period; and
  - 10.4.3 the difference between the two Exchange Rates (expressed as a percentage) (the "**Exchange Rate Percentage Difference**"); and
  - 10.4.4 the "**Price Adjustment**", being the Price multiplied by the Exchange Rate Percentage Difference.

- 10.5 If the Exchange Rate Percentage Difference is greater than [\*] in either direction, then the parties shall amend the Price by adding or subtracting the Price Adjustment as applicable, with such amendment to take effect on the last day of the calendar month following the month in which one party notified the other of the deviation in the Exchange Rate under clause 10.4 .
- 10.6 All sums due under this Agreement are exclusive of any applicable value added or other sales tax, which the Customer will pay in addition at the rate prescribed by law. The invoice shall be paid in full and the Customer has no right to withhold taxes, currency conversion charges or any other sums for payment due under invoice.
- 10.7 If any payment to Owen Mumford under this Agreement is overdue, Owen Mumford may charge the Customer interest on any overdue sum at the rate of [\*] above the base rate quoted by Barclays Bank Plc from time to time provided that if the payment of any amount is disputed by the Customer, the Customer shall only be obliged to pay the amount of the invoice not in dispute until the dispute has been resolved. In the case of dispute, interest shall only be payable on the amount which is not disputed unless the Customer is found to be liable for the amount due in which case the Customer shall reimburse Owen Mumford for the amount outstanding plus interest at the rate set out above from the date the original invoice was due to the actual date of payment.
- 10.8 If any Customer payment under this Agreement is at least [\*] overdue, Owen Mumford may, at its sole discretion, suspend work on manufacture and/or supply of Final Combination Product in accordance with any other Purchase Order until the payment has been made in full.

## **11 Intellectual Property**

- 11.1 Nothing in this Agreement will affect the ownership of any Intellectual Property Rights of either of the parties existing prior to this Agreement nor operate to grant to the other party any licence or right under any Intellectual Property Rights except as expressly set out in this Agreement. Owen Mumford acknowledges that the Customer owns the trade dress in the Final Combination Product and any Intellectual Property Rights relating thereto and undertakes not to use the same colour combinations used for the Final Combination Product for the manufacture or supply of auto-injector products for other customers in the Field at any time during the Term.
- 11.2 With respect to any inventions that occur during the conduct of activities described in this Agreement, any Intellectual Property Rights [\*] and/or [\*] shall be owned by [\*]. Any Intellectual Property Rights [\*] and/or [\*] shall be owned by [\*].
- 11.3 Subject to clauses 11.1 and 11.2, any Intellectual Property Rights associated with new inventions related solely to the Drug or to any improvements or modifications made to the Final Combination Product Primary Packaging, Secondary Packaging, labelling, leaflets, trademarks or any Customer Materials during the Term shall be owned by the Customer. The Customer grants to Owen Mumford a non-exclusive, royalty-free, non-sub-licensable (other than to Owen Mumford's sub-contractors for the performance of this Agreement) licence under its Intellectual Property Rights to use the Customer Materials and Confidential Information supplied to Owen Mumford by the Customer and any improvements or modifications made to the Final Combination Product solely for the purpose of the manufacture of the Devices and the assembly and supply of the Final Combination Product for the Customer during the Term. Such licence includes a

licence to any Customer Primary Packaging, Secondary Packaging, labelling, leaflets, trademarks or trade names where such licence is required for the manufacture of the Devices and the assembly and supply of the Final Combination Product .

- 11.4 To the extent necessary to enable the Customer to import, keep, offer for sale, sell and use the Final Combination Product supplied to it by Owen Mumford in the Field, Owen Mumford grants to the Customer an exclusive, irrevocable, sub-licensable, world-wide licence in the Field under Owen Mumford's Intellectual Property Rights within or covering the Device and the Final Combination Product. Notwithstanding the foregoing, in accordance with clause 4.6, Owen Mumford's intellectual property grant shall be narrowed to the Limited Field if Customer fails to purchase the Minimum Order Quantity and declines to pay the Order Shortfall Payment in any twelve (12) month period.
- 11.5 For any new inventions relating to both [\*] and [\*], resultant Intellectual Property Rights shall be jointly owned by Owen Mumford and Customer, each having an equal undivided interest therein (" **Joint IPR** "). Neither party may exploit, license, transfer or apply for registration of such Joint IPR except as expressly set out in this Agreement (or any other agreement between the parties).
- 11.6 Each party grants to the other party a non-exclusive, royalty-free, sub-licensable licence under its interest in the Joint IPR to the extent necessary to complete all activities contemplated under this Agreement (which shall include, in the case of Owen Mumford's activities, the right to sub-licence to its sub-contractors).
- 11.7 In the event of any Joint IPR arising under this Agreement the parties enter into a separate agreement governing their respective rights to exploit, license, transfer, and/or apply for registration of such Joint IPR.
- 11.8 Each party will notify the other party in writing if it becomes aware of any patent or patent application belonging to any third party that might adversely impact the manufacture of the Devices or the assembly or supply of Final Combination Product to the Customer or the sale or use of such Final Combination Product by the Customer.
- 11.9 Following receipt of written notification in accordance with clause 11.8, the parties will discuss in good faith the consequences of any third party patent or patent application identified and the parties will, at the option and cost of the Customer either:
- 11.9.1 propose a re-design of the Device and/or the Final Combination Product to avoid the infringement or potential infringement;
  - 11.9.2 enter into negotiations with such third party to obtain a licence to allow Owen Mumford to manufacture the Device and/or assemble and supply the Final Combination Product to the Customer and the Customer to use and sell the Final Combination Product in the Field; or

Until such redesign is complete or infringement avoided the Customer shall be relieved of its obligation to purchase the Minimum Order Quantity (which shall be reduced on a pro rata basis) and Owen Mumford shall be relieved of its obligation to supply the Final Combination Product.

- 11.10 Owen Mumford does not make any representation and gives no warranty that the use of the Final Combination Product by the Customer or any other person will

not infringe the Intellectual Property Rights or other rights of any third party and Owen Mumford will have no liability to the Customer for any such claim .

- 11.11 The Customer does not make any representation and gives no warranty that the manufacture of the Device and/or the assembly and supply of the Final Combination Product by Owen Mumford or any other person will not infringe the Intellectual Property Rights or other rights of any third party and the Customer will have no liability to Owen Mumford for any such claim.
- 11.12 Customer warrants at the Effective Date that, as far as it is aware, there are no third party Intellectual Property Rights or restrictions affecting the use or supply of the Customer Materials or Customer Confidential Information.
- 11.13 Owen Mumford warrants at the Effective Date that, as far as it is aware, there are no third party Intellectual Property Rights or restrictions affecting the manufacture of the Devices, the assembly of the Final Combination Product or the use or supply of the Final Combination Product by or to the Customer.

## **12 Confidentiality**

- 12.1 During the Term and for a period of [\*] after the expiry or termination of this Agreement each party will keep the Confidential Information of the other party in strict confidence, not disclose it to any third party and not use it for any purpose other than fulfilling its obligations under this Agreement.
- 12.2 Notwithstanding clause 12.1 the receiving party may disclose the Confidential Information of the disclosing party to those of its employees or sub-contractors who reasonably need to know it in order to fulfil the receiving party's obligations under this Agreement, provided that they are informed of the confidential nature of the Confidential Information and are bound by obligations of confidence no less onerous than those set out in this Agreement in respect of it. The receiving party will be liable to the disclosing party for any unauthorised disclosure or use of its Confidential Information by any of its employees or sub-contractors.
- 12.3 The obligations of confidence and non-use set out in clause 12.1 will not apply to any Confidential Information that the receiving party can show by reference to written records:
  - 12.3.1 was, at the time of disclosure to the receiving party, published, known publicly or otherwise in the public domain;
  - 12.3.2 is, after disclosure to the receiving party, published or becomes known publicly or otherwise becomes part of the public domain, through no fault of the receiving party, any of its Affiliates, any of its sub-contractors or any of their respective employees;
  - 12.3.3 was, prior to the time of disclosure to the receiving party, known to and at the free disposal of the receiving party;
  - 12.3.4 is, at any time, disclosed to the receiving party by a third party in circumstances in which the receiving party has no reason to believe that there has been a breach of an obligation of confidence owed to the disclosing party;
  - 12.3.5 is independently developed by or on behalf of the receiving party without use of or reliance on the Confidential Information received from the disclosing party.

- 12.4 Neither party will be in breach of its obligations under clause 12.1 to the extent that it is required to disclose any Confidential Information of the other under any law or by or to a court or other public, regulatory or financial authority that has jurisdiction over it, provided that the receiving party gives the disclosing party written notice prior to disclosing any of the disclosing party's Confidential Information and that the disclosure is made only to the extent required and for the purpose of complying with the requirement and that the receiving party takes all reasonable measures to ensure, as far as it is possible to do so, the continued confidentiality of any Confidential Information so disclosed.
- 12.5 Except as required to comply with applicable laws and regulations relating to the sale of the Final Combination Product (including, for the avoidance of doubt, any requirement for the Customer to refer to Owen Mumford as the manufacturer of the Final Combination Product), neither party will use the other's name or logo in any press release or product advertising, or for any other promotional purpose, without first obtaining the other's written consent.
- 12.6 On termination or expiry of this Agreement, each party will return to the other party all of that party's Confidential Information which is in its possession or under its control (including all copies). As an exception to this obligation, each party may retain one copy of the other party's Confidential Information in paper form in its legal files solely for the purpose of ensuring compliance with its obligations under this Agreement or as required to comply with any applicable legal or regulatory requirement including GMP.

### **13 Liability and Insurance**

- 13.1 Owen Mumford will indemnify the Customer, its Affiliates, its employees, officers and representatives and keep them fully and effectively indemnified against all losses, liabilities, damages and expenses (including reasonable legal fees and costs) suffered or incurred in connection with any claims, demands, actions or other proceedings brought against any of them by any third party arising directly out of any breach by Owen Mumford of the warranty in clause 2.8 - except to the extent that such losses, liabilities, damages or expenses are attributable to any negligence, breach of contract or wilful misconduct on the part of the Customer or its representatives or are attributable to the use of any Drug or any directions or specification from the Customer or to any modifications made at the request of the Customer in writing.
- 13.2 The Customer will indemnify Owen Mumford, its Affiliates, its employees and its officers and keep them fully and effectively indemnified against all losses, liabilities, damages and expenses (including reasonable legal fees and costs) suffered or incurred in connection with any claims, demands, actions or other proceedings brought against any of them by any third party arising directly out of or in connection with the manufacture, sale or use of any Final Combination Product (or any Drug contained within that Final Combination Product) or, where used in accordance with the Customer's written instructions, the use of any Customer Materials (including any Customer trademarks or trade names), except to the extent that such losses, liabilities, damages or expenses are attributable to any negligence, breach of contract or wilful misconduct on the part of Owen Mumford, its Affiliates, employees, officers or its representatives.
- 13.3 The party or person claiming the indemnity under clauses 13.1 and 13.2 shall:
- 13.3.1 promptly notify the indemnifying party in writing with details of the claim;

- 13.3.2 not make any admission in relation to the claim;
- 13.3.3 allow the indemnifying party to have the conduct of the defence or settlement of the claim; and
- 13.3.4 give the indemnifying party all reasonable assistance (at the indemnifying party's expense) in dealing with the claim.
- 13.4 In the event the party claiming the indemnity under clauses 13.1 and 13.2 fails to comply with clause 13.3 the amount that party may claim under the indemnity shall be reduced to take into account any additional loss that may have resulted in the claiming party's non-compliance with clause 13.3.
- 13.5 Subject to clause 13.7 and except under the indemnities in clauses 13.1 and 13.2, the liability of either party to the other for any breach of this Agreement, for any negligence or arising in any other way out of the subject matter of this Agreement will not extend to any indirect damages or losses, or any loss of profits, loss of revenue, loss of data, loss of contract or opportunity, or cost of replacement or correction of Customer Materials whether direct or indirect, even if the party bringing the claim has advised the other of the possibility of those losses, or if they were within the other parties' contemplation.
- 13.6 Subject to clause 13.7 and except under the indemnities in clauses 13.1 and 13.2, the aggregate liability of each party to the other for all and any breaches of this Agreement, any negligence or arising in any other way out of the subject matter of this Agreement will not exceed in total [\*] the amount of all payments made to Owen Mumford by the Customer under this Agreement in the [\*] immediately preceding the date of any claim.
- 13.7 Nothing in this Agreement limits or excludes either party's liability for:
- 13.7.1 death or personal injury caused by its negligence;
- 13.7.2 any fraud by that party; or
- 13.7.3 any sort of liability that, by law, cannot be limited or excluded.
- 13.8 The express undertakings and warranties given by the parties in this Agreement are in lieu of all other warranties, conditions, terms, undertakings and obligations whether express or implied by statute, common law, custom, trade usage, course of dealing or in any other way. All of these are expressly excluded from this Agreement to the full extent permitted by law.
- 13.9 During the Term and for a period of [\*] years after the expiry or termination of this Agreement, each party will maintain with a reputable insurance company comprehensive third party liability insurance including, without limitation, insurance of product liability with cover of at least [\*] per claim and in aggregate per year. Each party will, at the request of the other, provide documentary evidence confirming the maintenance of such cover.
- 13.10 Each party shall promptly notify the other party on becoming aware of any incidence involving the Final Combination Product resulting directly or indirectly in an incident or near incident contemplated by Article 10 of the Medical Devices Directive (EC Directive 93/442/EEC) as amended from time to time, or personal injury, death or damage to property or any side effect associated with the Final Combination Product. The parties agree to cooperate in relation to the investigation or any incident or side effect and shall make available as required all

statements, reports, tests and other relevant information so far as such is reasonably necessary . Any supply of information or provision of assistance under this clause 13.10 shall not constitute an assumption of liability with respect to such incident or side effect. Any admission or declaration of liability in relation to any incident or side effect shall only be made with the other party's prior written consent.

## **14 Adverse Events and Recalls**

- 14.1 Owen Mumford shall be responsible for investigation (including the requirement for the submission of reports to regulatory agencies) of any complaints (including as relevant, any adverse events) relating to the Final Combination Product unless it is attributable solely to the Drug, the combination or use of the Drug within the Final Combination Product, any components, cartridges or parts supplied or designed by the Customer, any directions or specification in writing received from the Customer or to any modifications made at the written request of the Customer. The Customer shall be responsible for investigation of any other complaints. The Parties agree to cooperate with each other as far as necessary to address any complaints including as relevant to provide information required by regulatory authorities.
- 14.2 In the event that either party has reason to believe a Final Combination Product should be recalled or withdrawn, it should immediately notify the other party in writing. Such notification shall include the reasons why the Final Combination Product should be recalled or withdrawn. The parties shall cooperate with each other in relation to any recall of Final Combination Product at their own cost.
- 14.3 Any recalls or withdrawals shall be conducted by the Customer at its cost provided that Owen Mumford shall reimburse the Customer for its direct and reasonable costs of recall if the recall or withdrawal is caused solely by the failure of the Final Combination Product to perform to the Specification, Owen Mumford's negligence or a breach by Owen Mumford of its obligations under this Agreement; such reimbursement shall be subject to clause 13.6 above.
- 14.4 If a competent authority requires a recall of the Final Combination Product, the parties shall cooperate in good faith to implement such recall provided always that the Customer shall have the right to control all recalls, product withdrawals and field corrections for the Final Combination Product. If the recall was caused:
- 14.4.1 solely or predominantly by Owen Mumford's failure to supply the Final Combination Product in accordance with the Specification or the provisions of this Agreement, the Customer shall be entitled to set its reasonable expenses incurred in a recall against its future payments due to Owen Mumford hereunder or, on request, to be reimbursed by Owen Mumford within [\*] of the date of the Customer's written request; or
  - 14.4.2 solely or predominantly by the Customer Materials, Owen Mumford shall be entitled to invoice the Customer for its reasonable expenses incurred in a recall.
- 14.5 Owen Mumford shall inform Customer of any adverse events reported to it involving the Final Combination Product as soon as reasonably possible and in no event later than two (2) Business Days from the time Owen Mumford becomes aware of such adverse event to ensure that Customer may comply with its expedited reporting obligations. Copies of the most current version of Owen Mumford's standard operating procedures for adverse events shall be supplied to the Customer.

## 15 Term and Termination

- 15.1 This Agreement will come into force on the Effective Date and will remain in force for a period ending on the date falling ten (10) years from the date on which the first shipment of Final Combination Product is accepted by Customer unless terminated earlier by either party in accordance with any other provision of this Agreement (the " **Term** "). No later than [\*] before the end of the Term the parties may agree in writing to continue the Agreement for an additional [\*] or such other period as the parties may agree.
- 15.2 Either party may (without limiting any other remedy it may have) at any time terminate this Agreement with immediate effect by giving written notice to the other if:
- 15.2.1 the other is in material breach of any provision of this Agreement and, if it is capable of remedy, the breach has not been remedied within [\*] after receipt of written notice specifying the breach and requiring its remedy; or
  - 15.2.2 the other party becomes insolvent, or if an order is made or a resolution is passed for its winding up (except voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of the other party's assets, or if the other party makes any arrangement with its creditors or ceases to carry on business or does or suffers any similar or analogous act existing under the laws of any country.
- 15.3 Either party may terminate this Agreement at any time without cause by giving not less than twelve (12) months' written notice to the other party.
- 15.4 In the event of termination of this Agreement by the Customer in accordance with clause 15.2 or Owen Mumford in accordance with clause 15.3:
- 15.4.1 Owen Mumford shall continue to manufacture the Devices and assemble and supply the Final Combination Product to the Customer in accordance with the terms of this Agreement and the Customer shall be permitted to continue to sell the Final Combination Product until the Customer is able to identify, appoint, and qualify through all necessary regulatory approvals a third party manufacturer to supply product equivalent to the Devices and the Final Combination Product in place of Owen Mumford; and
  - 15.4.2 on such commercial terms as the parties may agree (and subject to the negotiation and agreement of such commercial terms) Owen Mumford will provide to the Customer such assistance, documentation and licences under Owen Mumford's relevant Intellectual Property Rights as may reasonably be required by the Customer or the third party manufacturer to enable the third party manufacturer to manufacture products equivalent to the Devices and the Final Combination Product (any such documentation shall be the Confidential Information of Owen Mumford and such provision will be subject to the Customer and such third party manufacturer entering such binding obligations of confidence and non-use as Owen Mumford may reasonably require in relation to such documentation and subject to the Customer ceasing to manufacture or have manufactured such Final Combination Products on the date on which the Term would have ended had the Agreement not been terminated); and

- 15.4.3 the Customer's obligation to purchase the Minimum Order Quantity in accordance with clause 4.4 shall not apply during any period during which Owen Mumford continues to supply Final Combination Products to the Customer pursuant to this clause 15.4 .
- 15.5 In the event of termination of this Agreement by Owen Mumford in accordance with clause 15.2 or by the Customer in accordance with clause 15.3, Owen Mumford shall have no obligation to provide the Customer with any assistance, documentation or license to allow for the transfer of the manufacture of the Final Combination Product to any third party, but may at its option do so subject to such commercial terms as the parties may agree.
- 15.6 On termination or expiry of this Agreement for any reason:
- 15.6.1 all invoices shall become immediately due and payable in accordance with the payment terms set out in clause 10;
  - 15.6.2 Owen Mumford shall continue to manufacture the Devices and to assemble and supply Final Combination Product in accordance with any Purchase Orders accepted by Owen Mumford prior to the date of termination or expiry. Owen Mumford shall be entitled to render invoices for such Final Combination Product supplied as of the date of termination or expiry;
  - 15.6.3 all licences shall immediately cease as at date of termination or expiry save where continuation of such licences is necessary for: (a) Owen Mumford to comply with its obligations under clauses 15.4 or 15.6.2; or (b) for the Customer to meet any third party orders for Final Combination Product existing as of the date of termination or expiry (save that such right shall only apply for a period of [\*] from the date of termination or expiry);
  - 15.6.4 any regulatory approvals relating to the Device or the Final Combination Product held by Owen Mumford shall be immediately transferred to the Customer, at the Customer's sole cost. Owen Mumford shall provide the Customer with any assistance necessary and execute any documents required to transfer the regulatory approvals to the Customer;
  - 15.6.5 the Confidential Information of the parties shall be returned to the other party in accordance with clause 12.6.
- 15.7 Termination of this Agreement will not release any party from any obligation or liability which has fallen due or arisen before the effective date of termination of the Agreement.
- 15.8 Clauses 1, 10, 11, 12, 13, 14, 15, and 17 will survive termination of this Agreement for whatever reason.

## 16 Force Majeure

- 16.1 Neither party will be liable to the other for any delay or non-performance of its obligations under this Agreement (other than a payment obligation) arising from any cause beyond that party's reasonable control, including but not limited to, acts of God, fire, explosion, weather, disease, war, insurrection, civil strife, riots, government action, power failure, earthquake or terrorism (" **Force Majeure Event** "). Upon being affected by a Force Majeure Event, a party will give written

notice of that Force Majeure Event to the other party as soon as practicable, indicating the nature, effect and likely duration of that Force Majeure Event.

16.2 The performance of the affected party's obligations, to the extent affected by the Force Majeure Event, will be suspended during the period that the Force Majeure Event persists, provided that if performance is not resumed within three (3) months either party may, at any time prior to the resumption of the obligations, terminate this Agreement with immediate effect by giving written notice to the other party.

## 17 General

17.1 Each party shall comply with all applicable laws in the course of performing its obligations or exercising its rights pursuant to this Agreement. Each party undertakes to comply with the provisions of any applicable law intended to prevent corruption and/or bribery (collectively " **Compliance Laws** ") and to adopt all appropriate measures to prevent violation of the Compliance Laws. Without limiting the foregoing, either party agrees that it will not, in the conduct of its performance under this Agreement, offer, pay, give or promise to pay or give, directly or indirectly, any payment or gift of any money or thing of value to: (i) any government official to influence any acts or decisions of such official or to induce such official to use his influence with any government to effect or influence the decision of such government in order to assist the party in its performance of its obligations under this Agreement or to benefit either of the parties; (ii) any political party or candidate for public office for such purpose; or (iii) any person if such party knows or has reason to know that such money or thing of value will be offered, promised, paid or given, directly or indirectly, to any official, political party or candidate for such purpose.

17.2 **Notices:** Any notice to be given under this Agreement must be in writing, may be delivered to the other party by any of the methods set out in the left hand column below, and will be deemed to be received on the corresponding day set out in the right hand column:

<b>Method of service</b>	<b>Deemed day of receipt</b>
By hand or courier	the day of delivery
By pre-paid first class post	the second Business Day after posting
By recorded delivery post	the next Business Day after posting
By fax (provided the sender's fax machine confirms complete and error-free transmission of that notice to the correct fax number)	the next Business Day after sending or, if sent before 16.00 (sender's local time) on the Business Day it was sent

The parties' respective representatives for the receipt of notices are, until changed by notice given in accordance with this clause, as follows:

**For Owen Mumford:**

**For the Customer:**

Name: Gavin Jones

Name: Legal Department

Address: BrookHill  
Woodstock  
OX20 1TU  
UK

Address: 4200 Bohannon Drive  
Suite 250  
Menlo Park  
CA 94025  
USA

Fax number: +441993 813466

Fax number: +1 650-618-2602

- 17.3 **Assignment/sub-contracting:** Neither party may assign or transfer this Agreement as a whole, or any of its rights or obligations under it, without first obtaining the written consent of the other party (not to be unreasonably withheld or delayed) provided that:
- 17.3.1 either party may, without the consent of the other party, assign all of its rights and obligations under this Agreement to an Affiliate or to any successor to that part of its business to which the subject matter of this Agreement relates. In the event a party assigns all of its rights and obligations under this Agreement to an Affiliate and such Affiliate ceases to be an Affiliate of the party, all of the assigned rights and obligations under this Agreement shall be transferred back to the relevant party; and
- 17.3.2 Customer may, without the consent of Owen Mumford, assign this Agreement to the purchaser or licensee in the event of the grant of a licence or sale of its business relating to the Final Combination Product.
- 17.4 **Illegal/unenforceable provisions:** If the whole or any part of any provision of this Agreement is void or unenforceable in any jurisdiction, the other provisions of this Agreement, and the rest of the void or unenforceable provision, will continue in force in that jurisdiction, and the validity and enforceability of that provision in any other jurisdiction will not be affected.
- 17.5 **Waiver of rights:** If a party fails to enforce, or delays in enforcing, an obligation of the other party, or fails to exercise, or delays in exercising, a right under this Agreement, that failure or delay will not affect its right to enforce that obligation or constitute a waiver of that right. Any waiver of any provision of this Agreement will not, unless expressly stated to the contrary, constitute a waiver of that provision on a future occasion.
- 17.6 **No agency:** Nothing in this Agreement creates, implies or evidences any partnership or joint venture between the parties, or the relationship between them of principal and agent. Neither party has any authority to make any representation or commitment, or to incur any liability, on behalf of the other.
- 17.7 **Entire agreement:** This Agreement (incorporating all Schedules) and any Quality Agreement entered into between the parties constitutes the entire agreement between the parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them (including, without limitation, any project proposal supplied by Owen Mumford) relating to its subject matter. In the event that the terms of the Quality Agreement are inconsistent with the terms of this Agreement, the terms of this Agreement shall prevail. Each party acknowledges that it has not entered into this Agreement on the basis of any warranty, representation, statement, agreement or undertaking except those expressly set out in this Agreement. Each party waives any claim for breach of this Agreement, or any right to rescind this Agreement in respect of, any representation which is not an express provision of this Agreement. However, this clause does not exclude any liability which either party may have to the other (or any right which either party may have to rescind this Agreement) in respect of any fraudulent misrepresentation or fraudulent concealment prior to the execution of this Agreement.

- 17.8 **Formalities:** Each party will take any action and execute any document reasonably required by the other party to give effect to any of its rights under this Agreement, or to enable their registration in any relevant jurisdiction within the Territory provided the requesting party pays the other party's reasonable expenses.
- 17.9 **Amendments:** No variation or amendment of this Agreement (including the Schedules) will be effective unless it is made in writing and signed by each party's representative.
- 17.10 **Third parties:** No one except a party to this Agreement has any right to prevent the amendment of this Agreement or its termination, and no one except a party to this Agreement may enforce any benefit conferred by this Agreement, unless this Agreement expressly provides otherwise. The indemnified parties specified in clauses 13.1 and 13.2 may directly enforce the indemnities in those clauses.
- 17.11 **Governing law:** This Agreement is governed by, and is to be construed in accordance with, [\*] law. The [\*] Courts will have exclusive jurisdiction to deal with any dispute which has arisen or may arise out of or in connection with this Agreement, except that either party may bring proceedings for an injunction in any jurisdiction.

**SIGNED by** the authorised representatives of the parties on the date set out at the head of this Agreement.

**SIGNED** for and on behalf of **OWEN MUMFORD LIMITED** : **SIGNED** for and on behalf of **VERSARTIS GMBH** :

Name Gavin Jones

Name Paul B. Westberg

Position Group Finance Director

Position Managing Director

Signature /s/ Gavin Jones

Signature /s/ Paul B. Westberg

## **S SCHEDULE 1**

### **Part 1**

#### **Device**

Description of device, including drawings highlighting any special features will be agreed by Owen Mumford and Customer before commencement of manufacturing of the Device.

### **Part 2**

#### **Labelling and Packaging Specifications**

Details of the Labelling and Packaging Specifications (including any branding requirements) for both Primary and Secondary Packaging will be agreed by Owen Mumford and Customer before commencement of manufacturing of the Device.

### **Part 3**

#### **Final Combination Product**

Details of the Final Combination Product (including any branding requirements) will be agreed by Owen Mumford and Customer before commencement of manufacturing of the Final Combination Product.

### **Part 4**

#### **Quality Agreement and Specifications and Assumptions**

Within 90 days of the Effective Date, Owen Mumford and Customer will execute a Quality Agreement related to manufacture of the Device and the Final Combination Product. Before commencement of manufacturing of the Device, the parties will agree technical specifications and design specifications relating to the Device and the Final Combination Product.

**SCHEDULE 2**

**Price and Payment Schedule**

Provisional Price for each of the Final Combination Product based on the device being packed in a twin pack:

	<b>Price (Pounds Sterling)</b>			
	<b>Subassemblies</b>	<b>Assembly</b>	<b>Packaging</b>	<b>Total</b>
Initial Production up to [*] units	[*]	[*]	[*]	[*]
Routine Production <[*]	[*]	[*]	[*]	[*]
>[*]	[*]	[*]	[*]	[*]
>[*]	[*]	[*]	[*]	[*]
>[*]	[*]	[*]	[*]	[*]

This pricing does include batch release testing with the exception of drug testing.

The parties shall agree a fixed Price for the Final Combination Products prior to production.

The parties shall meet within [\*] before or after [\*], and each [\*] anniversary of that date (in each case the " **Anniversary** ") to review the Price in good faith.

If within one month of meeting to review the Price the parties cannot agree a revised Price, then, on such date of the Price will [\*] between the date on which the Price was last set or increased and the date on which Owen Mumford increases the Price.

Once the new Price is agreed or determined, it shall apply with effect from the relevant Anniversary and shall be deemed to come into force from that date (which, for the avoidance of doubt, may have retrospective effect if the parties meet, or if the Price is agreed or determined, after the relevant Anniversary). Within one month of agreeing or determining the new Price, the Customer shall pay to Owen Mumford any outstanding sums due in respect of its purchases of Products since the relevant Anniversary, together with any applicable VAT.

The Customer's address for the receipt of invoices under this Agreement is:

Accounts Payable

4200 Bohannon Drive, Suite 250

Menlo Park, CA 94025

USA

or

[ap@versartis.com](mailto:ap@versartis.com)

134906374 v2

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

I, Jay Shepard, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Versartis, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have :
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2016

/s/ Jay Shepard  
Jay Shepard  
Chief Executive Officer

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

I, Joshua Brumm, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Versartis, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have :
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2016

/s/ Joshua Brumm

Joshua Brumm

Chief Financial Officer

**CERTIFICATION**

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

1. The Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2016, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 2, 2016

In Witness Whereof, the undersigned have set their hands hereto as of the 2<sup>nd</sup> day of August, 2016.

/s/ Jay Shepard

Jay Shepard  
Chief Executive Officer

/s/ Joshua Brumm

Joshua Brumm  
Chief Financial Officer