Versartis, Inc.
Form 10-Q
November 07, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2014

OR

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

Commission file number: 001-36361

Versartis, Inc.

(Exact name of registrant as specified in its charter)

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

4200 Bohannon Drive, Suite 250

Menlo Park, California 94025

(650) 963-8580

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 x 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 ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of October 31, 2014, there were 24,194,808 outstanding shares of common stock, par value $0.0001 per share, of Versartis, Inc.

VERSARTIS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED September 30, 2014

PART I. FINANCIAL INFORMATION

PART 1. FINANCIAL INFORMATION

Item 1. Financial Statements

VERSARTIS, INC.

(A development stage company)

CONDENSED BALANCE SHEETS

(unaudited)

(in thousands, except share and per share data)

	September 30, 2014	December 31, 2013
Assets		
Current Assets		
Cash and cash equivalents	$ 181,582	$ 13,288
Prepaid expenses and other current assets	3,121	978
Total current assets	184,703	14,266
Other assets	285	396
Property and equipment, net	534	21
Total assets	$ 185,522	$ 14,683
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts Payable	$ 244	$ 315
Accrued liabilities	4,045	3,668
Total Current Liabilities	4,289	3,983
Convertible preferred stock warrant liability	-	474
Convertible preferred stock call option liability	-	21
Total Liabilities	4,289	4,478
Commitments and contingencies (Note 6)		
Convertible preferred stock, $0.0001 par value; 5,000,000, and 135,816,462 shares authorized at September 30, 2014 and December 31, 2013, respectively; zero and 120,648,174 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively; zero and $60,392 liquidation preference at September 30, 2014 and December 31, 2013 respectively	-	57,497
Stockholders' equity (deficit)		
Common stock, $0.0001 par value, 50,000,000 and 15,652,174 shares authorized at	2	—

September 30, 2014 and December 31, 2013, respectively; 24,194,808 and 1,257,311 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		
Additional paid-in capital	276,837	6,454
Deficit accumulated during the development stage	(95,606)	(53,746)
Total stockholders' equity (deficit)	181,233	(47,292)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$185,522	$14,683

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

VERSARTIS, INC.

(A development stage company)

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative Period From December 10, 2008 (Date of Inception) to September 30,
	2014	2013	2014	2013	2014
Operating expenses					
Research and development	$10,515	$4,576	$21,006	$11,401	$ 66,879
General and administrative	3,577	685	9,167	2,023	$ 19,309
Total operating expenses	14,092	5,261	30,173	13,424	86,188
Loss from operations	(14,092)	(5,261)	(30,173)	(13,424)	(86,188)
Interest income	50	—	89	—	93
Interest expense	—	—	—	(128)	(863)
Other income (expense), net	208	252	(11,776)	869	(9,746)
Net loss and comprehensive loss	(13,834)	(5,009)	(41,860)	(12,683)	(96,704)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	—	—	(25,559)	—	(25,559)
Accretion of Series A preferred stock to redemption value, net of extinguishment	—	—	—	—	1,098
Net loss attributable to common stockholders	$(13,834)	$(5,009)	$(67,419)	$(12,683)	$ (121,165)
Net loss per basic and diluted share attributable to common stockholders	$(0.57)	$(19.98)	$(3.93)	$(71.34)	
Weighted-average common shares used to compute basic and diluted net loss per share	24,194,808	250,745	17,137,647	177,777	

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

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VERSARTIS, INC.

(A development stage company)

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine Months Ended		Cumulative Period From December 10, 2008 (Date of Inception) to September 30, 2014
	September 30, 2014	2013	
Cash flows from operating activities			
Net loss	$(41,860)	$(12,683)	$(96,704)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	59	12	152
Loss on sale of assets	26	—	34
Reserve for uncollectible receivables	—	—	52
Stock-based compensation expense	3,049	144	3,600
Amortization of debt discount	—	121	666
Non-cash interest expense	—	7	195
Non-cash research and development expense	—	—	1
Remeasurement of convertible preferred stock call option liability	9,560	(863)	7,464
Remeasurement of convertible preferred stock warrant liability	2,279	(1)	2,239
Changes in assets and liabilities			
Accounts receivable	—	84	—
Prepaid expenses and other assets	(2,030)	(75)	(3,350)
Accounts payable	(71)	(251)	244
Accrued liabilities and other liabilities	377	1,073	4,045
Net cash used in operating activities	(28,611)	(12,432)	(81,362)
Cash flows from investing activities			
Proceeds from sale of property and equipment	—	—	10
Purchase of property and equipment	(600)	(9)	(785)
Security deposit for facility lease	—	—	(55)
Net cash used in investing activities	(600)	(9)	(830)
Cash flows from financing activities			
	132,138	—	132,138

Proceeds from issuance of common stock in initial public offering, net of issuance costs			
Proceeds from sale of option for Series A preferred stock purchase rights	—	—	1,000
Proceeds from issuance of convertible preferred stock, net of issuance costs	64,793	20,165	120,113
Proceeds from exercise of convertible preferred stock warrants	570	—	1,470
Proceeds from exercise of common stock options	4	27	53
Proceeds from issuance of convertible notes payable	—	—	9,000
Net cash provided by financing activities	197,505	20,192	263,774
Net increase in cash and cash equivalents	168,294	7,751	181,582
Cash and cash equivalents at beginning of period	13,288	329	—
Cash and cash equivalents at end of period	$181,582	$8,080	$ 181,582
Supplemental disclosure			
Cash paid for interest	$—	$—	$ 2
Supplemental disclosure of noncash items			
Conversion of notes payable and accrued interest to preferred stock	$—	$4,588	$ 9,195
Conversion of preferred stock call option liability to additional paid in capital	$9,581	$—	$ 9,581
Conversion of preferred stock warrant liability to additional paid in capital	$2,753	$—	$ 2,753
Conversion of preferred stock to common stock and additional paid in capital	$122,290	$—	$ 122,290
Issuance of warrants for preferred stock in connection with convertible notes	$—	$433	$ 666
Accretion of Series A convertible preferred stock to redemption value	$—	$—	$ 11,002
Issuance of call options related to convertible preferred stock	$—	$990	$ 3,504
Extinguishment of Series A convertible preferred stock	$—	$—	$ 12,100

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

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED) (unaudited)

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (unaudited)

1. Formation and Business of the Company

Versartis, Inc., (the "Company") a development stage 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 early clinical trials, filing patent applications, obtaining regulatory approvals, hiring personnel, and raising capital to support and expand these activities.

Unaudited Interim Financial Information

The accompanying financial information as of September 30, 2014 is unaudited. The Condensed Financial Statements included in this report reflect all adjustments (consisting only of normal recurring adjustments) that management considers necessary for the fair presentation of the results of operations for the interim periods covered and of the financial condition of the Company at the date of the interim balance sheet. The December 31, 2013 Condensed 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 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, 2013 included in the Company's prospectus filed pursuant to Rule 424(b)(4) on March 21, 2014 with the U.S. Securities and Exchange Commission ("SEC").

Initial Public Offering

In March 2014, the Company completed its initial public offering of shares of its common stock, or IPO, pursuant to which the Company issued 6,900,000 shares of common stock, which includes shares issued pursuant to the underwriters' exercise of their over-allotment option, and received net proceeds of approximately $132.1 million, after underwriting discounts, commissions and offering expenses. In addition, in connection with the completion of the Company's IPO, all convertible preferred stock converted into common stock. Effective with the closing of the IPO, the Company's Amended and restated Certificate of Incorporation authorizes the Company to issue 50.0 million shares of common stock and 5.0 million shares of preferred stock.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying financial statements have been prepared in accordance with GAAP and following the rules and regulations of the SEC for interim reporting. As permitted under those rules, certain disclosures or financial information that are normally required by GAAP can be condensed or omitted. The preparation of the accompanying financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

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.

Reclassification

Certain amounts within the condensed consolidated balance sheet for the prior period have been reclassified to conform with the current period presentation. These reclassifications had no impact on the Company’s previously reported financial position.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED) (unaudited)

Reverse Stock Split

On March 6, 2014, the Company effected a 1-for-11.5 reverse stock split of the Company's issued and outstanding shares of common stock. The par value of the common stock was not adjusted as a result of the reverse stock split. All issued and outstanding common stock share and per share amounts included in the accompanying financial statements have been adjusted to reflect this reverse stock split for all periods presented, and the conversion ratio of the preferred stock was adjusted accordingly.

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 four financial institutions that management believes are of high credit quality. Such deposits may, at times, exceed federally insured limits.

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 complete clinical studies and 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 September 30, 2014 the Company's cash and cash equivalents were held in four institutions in the United States and include deposits in money market funds which were unrestricted as to withdrawal or use. At December 31, 2013, the Company's cash and cash equivalents were held in an institution in the United States and include deposits in a money market fund which was unrestricted as to withdrawal or use. Included in cash and cash equivalents at September 30, 2014 and December 31, 2013 was approximately $0.1 million of restricted cash held by a bank as security for the Company's credit cards.

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 September 30, 2014, December 31, 2013, or the cumulative period from December 10, 2008 (date of inception) to September 30, 2014.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED) (unaudited)

Fair Value of Financial Instruments

The carrying value of the Company's cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to the short-term nature of these items. Convertible preferred stock call option liability and convertible preferred stock warrant liability were carried at fair value.

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

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

Level I Unadjusted quoted prices in active markets for identical assets or liabilities;

Level II Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level III Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.
The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company's financial instruments consist of Level I assets and Level III liabilities. Level I securities are comprised of a highly liquid money market fund. Level III liabilities that are measured at fair value on a recurring basis consist of convertible preferred stock warrant liability and convertible preferred stock call option liability. The fair values of these instruments are measured using an option pricing model. Inputs used to determine estimated fair market value include the estimated fair value of the underlying stock at the valuation measurement date, the remaining expected term of the instrument, risk-free interest rates, expected dividends and the expected volatility.

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.

Convertible Preferred Stock Warrants

The Company accounted for its convertible preferred stock warrants as liabilities based upon the characteristics and provisions of each instrument. Convertible preferred stock warrants classified as derivative liabilities were recorded on the Company's balance sheet at their fair value on the date of issuance and revalued on each subsequent balance sheet, with fair value changes recognized as increases or reductions to other income (expense), net in the condensed statements of operations.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED) (unaudited)

Prior to the IPO in March 2014, the Company had outstanding warrants which were classified as a liability and remeasured to fair value each reporting period. The Company had estimated the fair value of these liabilities using an option pricing model and assumptions that were based on the individual characteristics of the warrants on the valuation date, as well as assumptions for expected volatility, expected life, dividends, and risk-free interest rate. Immediately prior to the completion of the Company's IPO in March 2014, all of the warrants were either exercised for cash or automatically net exercised for a total issuance of 158,179 shares of common stock, pursuant to the terms of the warrants. Just prior to the exercises, all outstanding warrants, covering 173,910 shares, were remeasured using the intrinsic value of the warrant computed as the difference between the $21.00 per share IPO price and the $5.17 per share exercise price of the warrant. The remeasurement of the fair value of these warrants from December 31, 2013 through the date of the conversion to a common stock warrant and following exercise resulted in a $2.3 million expense recorded to other income (expense), net in our condensed statement of operations. The resulting fair value of approximately $2.8 million was reclassified to additional paid in capital upon completion of the IPO.

Convertible Preferred Stock Call Option

The Company determined that the Company's obligation to issue, and the investors' obligation to purchase, additional shares of the Company's convertible preferred stock represented a freestanding financial instrument. The freestanding convertible preferred stock call option liability was initially recorded at fair value, with fair value changes recognized as increases or reductions to other income (expense), net in the condensed statement of operations. At the time of the deemed exercise of the call option, the remaining value of the option was reclassified to additional paid in capital. Immediately prior to the Series D-2 financing completed in February 2014, the Company remeasured the fair value of the preferred stock call option liability associated with the Series D convertible preferred stock financing and recorded other expense of approximately $9.6 million in the condensed statement of operations. Fair value was computed using a discount from the Company's public offering price less the liquidation value of the underlying Series D convertible preferred stock.

Convertible Preferred Stock

The Company classified the convertible preferred stock as temporary equity on the balance sheets due to certain change in control events that are outside the Company's control, including liquidation, sale or transfer of the Company, as holders of the convertible preferred stock can cause redemption of the shares. Upon the IPO in March 2014, all of the outstanding shares of convertible preferred stock automatically converted into 15,876,104 shares of common stock.

In February 2014, the Company issued 48,758,857 shares of its Series E convertible preferred stock at a purchase price of $1.128 per share for an aggregate purchase price of approximately $55.0 million. The shares of convertible preferred stock automatically converted into 4,239,984 shares of common stock upon completion of the Company's IPO. Pursuant to Accounting Standards Codification 470-20, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios, to Certain Convertible Instruments, the Company recorded a deemed dividend of approximately $25.6 million, which reflected a beneficial conversion feature on the underlying Series E preferred stock, in connection with the closing of the IPO on March 26, 2014.

Research and development

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

Income taxes

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

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED) (unaudited)

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 statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative Period From December 10, 2008 (Date of Inception) to September 30,
	2014	2013	2014	2013	2014
Operating Expenses					
Research and development	$394	$ 34	$761	$88	$ 1,130
General and administrative	1,162	21	2,288	56	2,470
Total	$1,556	$ 55	$3,049	$144	$ 3,600

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. There have been no items qualifying as other comprehensive loss and, therefore, for all periods presented, the Company's comprehensive loss was the same as its reported net loss.

Net Loss per Share of Common Stock

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, convertible preferred stock, convertible notes payable, stock options and convertible preferred stock warrants 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.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED) (unaudited)

In June 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014-10, Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation, or ASU 2014-10, which eliminates the definition of a development stage entity, the development stage presentation and disclosure requirements under ASC 915, Development Stage Entities, and amends provisions of existing variable interest entity guidance under ASC 810, Consolidation. As a result of the changes, the financial statements of entities which meet the former definition of a development stage entity will no longer: (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. Furthermore, ASU 2014-10 clarifies disclosures about risks and uncertainties under ASC Topic 275, Risks and Uncertainties that apply to companies that have not commenced planned principal operations. Finally, variable interest entity rules no longer contain an exception for development stage entities and, as a result, development stage entities will have to be evaluated for consolidation in the same manner as non-development stage entities.

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.

Under ASU 2014-10, entities are no longer required to apply the presentation and disclosure provisions of ASC 915 during annual periods beginning after December 15, 2014. In addition, the revisions to the consolidation standards are effective for annual periods beginning after December 15, 2015 for public companies and are effective for annual periods beginning after December 15, 2016 for nonpublic entities. Early adoption is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued (public business entities) or made available for issuance (other entities). The Company is currently evaluating the impact of adopting ASU 2014-10, but does not expect there to be any impact on its financial position, results of operations or cash flows.

3. Balance Sheet Components

Prepaid expenses and other current assets (in thousands)

	September 30, 2014	December 31, 2013
Preclinical and clinical [1]	$ 2,128	$ 847
Other	993	131
Total	$ 3,121	$ 978

(1) A substantial majority of these prepayments consist of advances to our contract manufacturers.

Accrued Liabilities (in thousands)

	September 30, 2014	December 31, 2013
Payroll and related	$ 1,264	$ 539
Preclinical and clinical	2,403	1,726
Professional services	103	1,265
Other	275	138
Total	$ 4,045	$ 3,668

VERSARTIS, INC.

(A development stage company)

NOTES TO 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 September 30, 2014 (unaudited)			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$175,083	$175,083	$ —	$—

	Fair Value Measurements at December 31, 2013			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$12,761	$12,761	$ —	$—
Liabilities				
Convertible preferred stock warrant liability	$474	$—	$ —	$474
Convertible preferred stock call option liability	21	—	—	21
Total liabilities	$495	$—	$ —	$495

The fair value measurement of the convertible preferred stock warrant liability and convertible preferred stock call option liability was based on significant inputs not observed in the market and thus represents a Level III measurement. Level III instruments are valued based on unobservable inputs that are supported by little or no market activity and reflect the Company's assumptions in measuring fair value. The Company's estimated fair value of the convertible preferred stock warrant liability was calculated using an option pricing model and key assumptions including the probabilities of settlement scenarios, enterprise value, time to liquidity, risk-free interest rates, discount for lack of marketability and volatility. The Company's estimated fair value of the preferred stock call option liability was calculated using an option pricing model and key assumptions including the estimated fair value of the Company's preferred stock, risk-free interest rates and volatility and the probability of the closing of the future financing tranche. The estimates were based, in part, on subjective assumptions.

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level III inputs. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the year ended December 31, 2013 or the nine month period ended September 30, 2014.

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VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED) (unaudited)

The following table sets forth a summary of the changes in the fair value of the Company's Level III financial instruments as follows (in thousands):

	Convertible preferred stock call option liability	Convertible preferred stock warrant liability
Balance at January 1, 2014	$ 21	$ 474
Fair value of call option liability recognized upon issuance of preferred stock	—	—
Change in fair value recorded in other income (expense), net	9,560	2,279
Conversion of preferred stock into common stock and reclassification to permanent equity	(9,581)	(2,753)
Balance at September 30, 2014	$ —	$ —

	Convertible preferred stock call option liability	Convertible preferred stock warrant liability
Balance at January 1, 2013	$ —	$ 433
Issuance of financial instruments	990	—
Fair value of call option liability recognized upon issuance of preferred stock	(127)	—
Change in fair value recorded in other income (expense), net	(863)	(1)
Balance at September 30, 2013	$ -	$ 432

5. Convertible Preferred Stock Warrants

In connection with the convertible note purchase agreements ("2010 Notes"), the Company issued convertible preferred stock warrants equal to 20% of the shares issuable upon conversion of the 2010 Notes. Using an option pricing model with a volatility of 85%, term of 1.75 years and a risk-free interest rate of 0.53%, the fair value of the warrants was determined to be approximately $233,000 and was recorded as warrant liability and a debt discount against the 2010 Notes and amortized to interest expense over the term of the 2010 Notes. The convertible preferred stock warrants were exercised in 2012 for 2.0 million shares of Series B convertible preferred stock at an exercise price of $900,000.

In connection with the convertible note purchase agreements ("2012 Notes"), the Company issued convertible preferred stock warrants equal to 20% of the shares issuable on conversion of the 2012 Notes. The convertible preferred stock warrants were exercisable into shares of the same class of convertible preferred stock issued upon conversion of the related 2012 Notes. The convertible preferred stock warrants had a five-year term and an expiration date of October 12, 2017. The estimated fair value of these warrants of $433,000 at issuance was recorded as a debt discount on the 2012 Notes, and amortized to interest expense using the effective interest method through the original maturity date in 2013. The convertible preferred stock warrants were valued using an option pricing model with a risk-free interest rate of 0.21%, volatility of 90%, and an expected life equal to 1.5 years. As of December 31, 2013, the fair

value of the warrants was estimated to be $474,000.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED) (unaudited)

The 2012 warrants remained unexercised as of December 31, 2013. The terms of the warrants provided that they would expire at the earlier of (i) the closing of an initial public offering, (ii) a sale of the company or (iii) October 12, 2017; provided that if a holder of the warrants does not notify us of the holder's intent to exercise or not to exercise the warrant prior to the expiration date, and the fair market value of the underlying shares on the expiration date is greater than the exercise price, then the holder will be deemed to have net exercised the warrant immediately prior to the expiration date. Upon the closing of our IPO, the warrants were exercised for a total of 158,179 shares of our common stock.

Prior to the IPO in March 2014, the Company had outstanding warrants which were classified as a liability and remeasured to fair value each reporting period. The Company had estimated the fair value of these liabilities using an option pricing model and assumptions that were based on the individual characteristics of the warrants on the valuation date, as well as assumptions for expected volatility, expected life, dividends, and risk-free interest rate. Immediately prior to the completion of the Company's IPO in March 2014, all of the warrants were either exercised for cash or automatically net exercised for a total issuance of 158,179 shares of common stock, pursuant to the terms of the warrants. Just prior to the exercises, all outstanding warrants, covering 173,910 shares, were remeasured using the intrinsic value of the warrant computed as the difference between the $21.00 per share IPO price and the $5.17 per share exercise price of the warrant. The remeasurement of the fair value of these warrants from December 31, 2013 through the date of the conversion to a common stock warrant and following exercise resulted in a $2.3 million expense recorded to other income (expense), net in our condensed statement of operations. The resulting fair value of approximately $2.8 million was reclassified to additional paid in capital upon completion of the IPO.

The assumptions used to value the convertible preferred stock warrants were as follows:

	December 31, 2013	
Expected term (in years)	1.1	
Expected volatility	75.00	%
Risk-free interest rate	13.00	%
Dividend yield	0	%

6. Commitments and Contingencies

Facility Leases

In August 2011, the Company signed an operating facility lease for its corporate office that included approximately 5,740 square feet of office space in Redwood City, California. The lease term was for thirty months and commenced in October 2011.

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 $1.6 million as of September 30, 2014.

7. Equity Incentive Plans

The Company's Board of Directors, or Board, and stockholders previously approved the 2009 Stock Plan, or the 2009 Plan. In March 2014, the stockholders approved the 2014 Equity Incentive Plan, or the 2014 Plan. As of March 21, 2014, the effective date of the 2014 Plan, the Company suspended the 2009 Plan and no additional awards may be granted under the 2009 Plan. Any shares of common stock covered by awards granted under the 2009 Plan that terminate after March 21, 2014 by expiration, forfeiture, cancellation or other means without the issuance of such shares, will be added to the 2014 Plan reserve.

As of September 30, 2014, the total number of shares of common stock available for issuance under the 2014 Plan was 4,100,255, which includes the 1,695,652 shares of common stock that were available for issuance under the 2009 Plan as of the effective date of the 2014 Plan. 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 September 30, 2014, approximately 648,000 shares of common stock were subject to outstanding awards under the 2014 Plan.

VERSARTIS, INC.

(A development stage company)

NOTES TO FINANCIAL STATEMENTS (CONTINUED) (unaudited)

In March 2014, the Board and stockholders approved the 2014 Employee Stock Purchase Plan, or the ESPP, which became effective as of March 5, 2014. The Company has 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 September 30, 2014, the Company has not issued any shares of common stock under the ESPP.

8. Net loss per share of Common Stock

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net loss attributable to common stockholders - basic and diluted	$(13,834)	$(5,009)	$(67,419)	$(12,683)
Weighted-average shares outstanding	24,194,808	250,991	17,137,647	178,023
Less: weighted average shares subject to repurchase	—	(246)	—	(246)
Weighted-average shares used to compute basic and diluted net loss per share	24,194,808	250,745	17,137,647	177,777
Basic and diluted net loss per common share	$(0.57)	$(19.98)	$(3.93)	$(71.34)

Basic net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net loss attributable to common stockholders per share is computed by dividing the net loss attributable to common stockholders 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 common 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:

	September 30,	
	2014	2013

Convertible preferred stock	—	8,945,252
Warrants to purchase convertible preferred stock (1)	—	173,910
Options to purchase common stock	2,477,446	828,382
Restricted stock units	104,821	—

(1) Assumes exercise of warrants to purchase convertible preferred stock at $5.17 per share.

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 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, 2013, included in our prospectus dated March 21, 2014, filed with the U.S. Securities and Exchange Commission (SEC) pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Prospectus").

Special note regarding forward-looking statements

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

Overview

Versartis, Inc. (the "Company" "We" "Our") is an endocrine-focused biopharmaceutical company initially developing our novel long-acting recombinant human growth hormone, 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 compliance, which in turn can lead to suboptimal treatment outcomes in GHD patients. VRS-317 is intended to reduce the burden of daily treatment by requiring significantly fewer injections, potentially improving compliance and, therefore, treatment outcomes. We have completed the Phase 2a stage of our pediatric GHD clinical trial in which we evaluated weekly, semi-monthly and monthly dosing regimens and have received feedback from various authorities, including the FDA and the European Medicines Agency, or EMA, providing guidance on the design of our planned Phase 3 clinical trial, which we intend to initiate by early 2015. We have also received feedback from the Japanese regulatory agency, Pharmaceuticals Medicines and Devices Agency, or PMDA, on our plans for a pediatric GHD Phase 2/3 clinical trial in Japan, which we also intend to initiate by early 2015. We have global rights to VRS-317 and, if VRS-317 is approved, given the highly concentrated prescriber base, we intend to commercialize it with our own specialty sales force in the United States and Canada, and potentially other geographies.

VRS-317 is a fusion protein consisting of rhGH and a proprietary half-life extension technology known as XTEN, which we in-license 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 VRS-317. 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.

First Nine Months of 2014 and Other Recent Highlights

On March 21, 2014, our registration statement on Form S-1 relating to our initial public offering (IPO) of common stock became effective. Our IPO closed on March 26, 2014 at which time we sold 6,900,000 shares of our common stock, which included 900,000 shares issued pursuant to the exercise in full by the underwriters of their over-allotment option. We received cash proceeds of approximately $132.1 million from the IPO, net of underwriting discounts and commissions and expenses paid by us.

Financial overview

Summary

We have not generated net income from operations, and, at September 30, 2014, we had an accumulated deficit of $95.6 million, primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments and research and development payments in connection with potential future strategic partnerships, we have not yet generated any revenue. VRS-317 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 VRS-317 into a Phase 3 clinical trial, 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 transition to and prepare for a potential Phase 3 clinical trial. 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 comprised of changes in the fair value of the convertible preferred stock warrant and call option liabilities. In addition, other income (expense), net includes any potential gains and losses on foreign currency transactions primarily related to third-party contracts with foreign based contract manufacturing organizations.

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 financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues 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 financial statements and in Note 1 to our audited financial statements contained in the prospectus filed pursuant to Rule 424(b)(4) on March 21, 2014 with the U.S. Securities and Exchange Commission ("Prospectus"). There have been no significant or material changes in our critical accounting policies during the three and nine months ended September 30, 2014, 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 Prospectus.

Results of operations

Comparison of the Three and Nine Months Ended September 30, 2014 and 2013

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

	Three Months Ended September 30,		Increase/ (Decrease)		Nine Months Ended September 30,		Increase/ (Decrease)	
	2014	2013			2014	2013		
Operating expenses:								
Research and development	$10,515	$4,576	$5,939	130%	$21,006	$11,401	$9,605	84 %
General and administrative	3,577	685	2,892	422%	9,167	2,023	7,144	353%
Loss from operations	(14,092)	(5,261)	8,831	168%	(30,173)	(13,424)	16,749	125%
Interest income	50	—	50	NM (1)	89	-	89	NM (1)
Interest expense	—	—	—	NM (1)	—	(128)	128	NM (1)
Other income (expense), net	208	252	(44)	-18 %	(11,776)	869	(12,645)	NM (1)
Not loss and comprehensive loss	$(13,834)	$(5,009)	$8,825	176%	$(41,860)	$(12,683)	$29,177	230%

(1) Not meaningful.

Research and development expense

Research and development expense increased $5.9 million, or 130%, to $10.5 million for the three months ended September 30, 2014 from $4.6 million for the same period in 2013. For the nine months ended September 30, 2014 research and development expense increased $9.6 million or 84%, to $21.0 million from $11.4 million in the same period in 2013. The increase in research and development expense was primarily due to a $5.5 million increase for the three-month period and $7.2 million for the nine-month period related to manufacturing costs to support our ongoing extension study and prepare for our Phase 3 clinical trial. Additionally, clinical costs increased $0.4 million for the three-month period and $2.4 million for the nine-month period to wrap-up our Phase 2a clinical study, support our ongoing extension study, and plan for a Phase 3 study. For the three months ended September 30, 2014 and 2013, substantially all of our research and development expense related to our VRS-317 drug development activity.

General and administrative expense

General and administrative expense increased $2.9 million, or 422%, to $3.6 million for the three months ended September 30, 2014 from $0.7 million for the same period in 2013. For the nine months ended September 30, 2014 general and administrative expense increased $7.1 million or 353%, to $9.2 million from $2.0 million in the same period in 2013. The increase in general and administrative expense was primarily due to additional payroll, including stock-based compensation, consulting, and professional services expenses incurred during the three- and nine-month periods ended September 30, 2014 as we prepared for and completed our initial public offering and expanded our infrastructure to support additional public company requirements.

Interest expense

Interest expense decreased $0.1 million, from $0.1 million for the nine months ended September 30, 2013 to zero for the same period in 2014. The decrease in interest expense was primarily due to interest expense associated with the October 2012 Convertible Loan Agreement, which converted into Series B convertible preferred stock in January 2013.

Other income (expense), net

Other income (expense), net decreased $12.6M to $11.8 million of other expense for the nine months ended September 30, 2014 from other income of $0.9 million for the same period in 2013. This decrease was primarily due to a change in the fair value of the preferred stock call option liability associated with the Series D convertible preferred stock financing of approximately $9.6 million as measured immediately prior to the Series D-2 financing completed in February 2014. Other expense in the nine months ended September 30, 2014 also includes a $2.3 million change in the fair value of the warrant liability associated with the Series B convertible preferred stock financings in January and May 2012 as measured immediately prior to the close of our IPO on March 26, 2014.

Liquidity and capital resources

On March 26, 2014, we completed an IPO of our common stock, which resulted in the sale of 6,000,000 shares at a price to the public of $21.00 per share. Also on March 26, 2014 the underwriters of our IPO exercised in full their over-allotment option to purchase an additional 900,000 shares of common stock at a price to the public of $21.00 per share. We received net proceeds from the IPO of approximately $132.1 million after deducting underwriting discounts and expenses paid by us. In connection with the IPO, all outstanding preferred stock warrants converted into warrants to purchase common stock and all of our outstanding convertible preferred stock automatically converted to common stock at a ratio of one-for-11.5 on March 26, 2014.

On February 4, 2014, we issued shares of our Series D-2 convertible preferred stock for gross proceeds of approximately $10.0 million. On February 14, 2014, we issued shares of our Series E convertible preferred stock for gross proceeds of approximately $55.0 million.

Since our inception and through the IPO, we have financed our operations primarily through private placements of our equity securities and debt financing. At September 30, 2014, we had cash and cash equivalents of $181.6 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 VRS- 317 and any additional product candidates. Specifically, we have incurred substantial expenses in connection with our Phase 2a clinical trial and we expect to continue to incur substantial expenses in connection with our extension trial and the Phase 3 clinical trials that we plan to conduct.

If our planned Phase 3 clinical trials for VRS-317 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 VRS-317 on a larger scale;
- the costs of commercialization activities if VRS-317 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:

	Nine Months Ended September 30,	
	2014	2013
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (28,611)	$ (12,432)
Investing activities	(600)	(9)
Financing Activities	197,505	20,192
Net increase in cash and cash equivalents	$ 168,294	$ 7,751

Cash used in operating activities

Net cash used in operating activities was $28.6 million and $12.4 million in the nine months ended September 30, 2014 and 2013, 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 2014 increased compared to 2013 primarily due to a higher net loss from operations as we continued to increase our research and development expenditures to develop VRS-317 and due to additional general and administrative expenditures as we prepared for and completed our initial public offering.

Cash used in investing activities

Cash used in investing activities consisted primarily of investment in equipment and leasehold improvements made to our new corporate headquarters in Menlo Park, California.

Cash provided by financing activities

Cash provided by financing activities was $197.5 million in the nine months ended September 30, 2014, compared to $20.2 million in the same period of 2013. Cash provided by financing activities in both years consisted of net proceeds from the issuance of convertible preferred stock plus the net proceeds of approximately $132.1 million from our IPO in 2014.

As of September 30, 2014, we had cash and cash equivalents of approximately $181.6 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 nine months ended September 30, 2014, 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 Prospectus, except for our entering into a new operating facility lease in March 2014. Under this 39-month lease agreement beginning in June 2014, we are obligated to pay approximately $1.6 million in lease payments over the term of the lease.

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 September 30, 2014, we had cash and cash equivalents of $181.6 million consisting of cash and investments in highly liquid U.S. money market funds. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are substantially all short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. Management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), as of the end of the period covered by this report. Based upon the evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures were effective to ensure that information required to be disclosed in the reports we file and submit under the Securities Exchange Act of 1934, as amended, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure.

A company's internal control over financial reporting is a process designed by, or under the supervision of, a company's principal executive and principal financial officers, or persons performing similar functions, and effected by a company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. In connection with our preparation for the March 2014 IPO, we concluded that there was a material weakness in our internal control over financial reporting that caused the restatement of our previously issued 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. 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 a company's annual or interim financial statements will not be prevented or detected on a timely basis. 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 company's structure and financial reporting requirements.

During the fourth quarter of 2013 and in preparation for the March 2014 IPO, we initiated various remediation efforts, including hiring additional resources with the appropriate public company and technical accounting expertise and taking other actions that are more fully described below. As such remediation efforts are still ongoing, we have concluded that the material weakness has not been remediated. Our remediation efforts to date have included the following:

Addition of employee resources. We are continuing to add appropriate resources to our finance team and have leveraged external consultants at times to facilitate accurate and timely accounting closes and to accurately prepare and review financial statements and related footnote disclosures. Our finance team has been expanded to include a Chief Financial Officer and a corporate controller, both with significant public company and biotechnology industry experience, as well as other qualified personnel.

Other actions to strengthen the internal control environment. As a result of the additional resources added to the finance function, we are allowing for separate preparation and review of the reconciliations and other account analyses. In addition, these additional finance resources are allowing us to develop a more structured close process, including enhancing our existing policies and procedures, to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including, but not limited to, those regarding proper financial statement classification, recognition of accruals to ensure proper period-end cutoff of expenses and assessing more judgmental areas of accounting.

The actions that have been taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. While we have implemented a plan to remediate this weakness, we cannot assure you that we will be able to remediate this weakness, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows. For additional information about this material weakness, see "Risk factors—Risks related to ownership of our common stock—We have 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 financial statements. If we fail to remediate one or more material weaknesses or if we fail to establish and maintain effective control over financial reporting, our ability to accurately report our financial results could be adversely affected."

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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 prospectus, including our financial statements and notes thereto, before you invest in our common stock. 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, VRS-317.

We do not have any products that have gained regulatory approval. Our only clinical-stage product candidate is VRS-317, a novel, long-acting recombinant human growth hormone, or rhGH, combined with a proprietary half-life extension technology referred to as XTEN. We have completed the Phase 2a stage of a Phase 1b/2a clinical trial in children with growth hormone deficiency (GHD) and intend to initiate our planned North American and European Phase 3 pediatric GHD clinical trial for VRS-317 by early 2015. We also plan to initiate a Phase 2/3 pediatric GHD clinical trial of VRS-317 in Japan by early 2015. 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 VRS-317 in a timely manner.

We cannot commercialize VRS-317 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 VRS-317 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 VRS-317 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 VRS-317 followed by most of the approved rhGH products for pediatric GHD patients: a dose-finding study and a Phase 3 registration trial with a primary endpoint of twelve month mean 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 VRS-317, due to its unique properties, will produce different results. If the three and six month mean height velocities that we observe for VRS-317 in the recently completed Phase 1b/2a clinical trial do not correlate to twelve month mean height velocities that we ultimately observe in any Phase 3 clinical trial that we may conduct, VRS-317 may not achieve the required primary endpoint in the Phase 3 clinical trial, and VRS-317 may not receive regulatory approval.

Moreover, obtaining regulatory approval for marketing of VRS-317 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 VRS-317 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 VRS-317 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 VRS-317 or our future product candidates, once obtained, may be withdrawn. Furthermore, even if we obtain regulatory approval for VRS-317, the commercial success of VRS-317 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 VRS-317 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 VRS-317;
- 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 VRS-317 as safe and effective by patients, caregivers and the medical community;
- a continued acceptable safety profile of VRS-317 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 VRS-317, we may not be able to earn sufficient revenues to continue our business.

VRS-317 is a new chemical 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.

VRS-317 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 VRS-317 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 VRS-317 compared to currently approved rhGH products is unknown, and it is possible it may increase the risk of unforeseen reactions to VRS-317 following extended treatment relative to other currently approved rhGH products. Elevated levels of rhGH and 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 VRS-317 could result in an increased immune response to rhGH, leading to a loss of efficacy or potential safety issues. If extended treatment with VRS-317 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 VRS-317.

Because the results of preclinical testing and earlier clinical trials and the results to date in the Phase 2a stage of our Phase 1b/2a clinical trial are not necessarily predictive of future results, VRS-317 may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical testing and early clinical trials does 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 for our Phase 2a stage of our Phase 1b/2a clinical trial of VRS-317 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 VRS-317. 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 or other later-stage clinical trial do not produce favorable results, our ability to achieve regulatory approval for VRS-317 may be adversely impacted.

There can be no assurance that VRS-317 will not exhibit new or increased safety risks in any potential Phase 3 clinical trial as compared to the Phase 1b/2a trial. 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 established the optimal dose for VRS-317. There can be no guarantee that the doses studied in the Phase 3 clinical trial that we may conduct will be efficacious or, if they are, whether any one will be the optimal dose. We believe we will need to conduct additional clinical trials to evaluate additional dose levels of VRS-317. In addition, we do not yet know how frequently VRS-317, if approved, will have to be administered. Our completed Phase 1b/2a clinical trial evaluated weekly, semi-monthly and monthly dosing regimens. There cannot be any guarantee that any of these studies will be successful in determining a dose or dose regimen of VRS-317 suitable for marketing approval.

As an organization, we have never conducted a Phase 3 clinical trial or submitted an NDA or BLA before, and may be unsuccessful in doing so for VRS-317.

We have completed the Phase 2a stage of a Phase 1b/2a clinical trial of VRS-317, however, the conduct of Phase 3 clinical trials and the submission of a successful Biologics License Application, or a 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 VRS-317. Failure to commence or complete, or delays in, our planned clinical trials would prevent us from or delay us in commercializing VRS-317.

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 VRS-317 will achieve success where others have failed.

Many attempts have been made to develop sustained release formulations of rhGH. For example, Nutropin Depot, a long-acting form of rhGH developed by Genentech that uses Alkermes' ProLease® injectable extended-release drug delivery system, was approved by the FDA in 1999 and withdrawn from the market in 2004 by Genentech and Alkermes due to the significant resources required to continue manufacturing and commercializing the product. Additional attempts at sustained release formulations have not yet led to globally marketed products, due to manufacturing, regulatory, efficacy and/or safety reasons. Even if we obtain all requisite regulatory approvals, no assurance can be given that VRS-317 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 VRS-317 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 VRS-317. The last patient was enrolled in the Phase 2a stage of the study in November 2013, and the study was completed by mid-2014. As the outcome of the Phase 2a stage of the trial was successful, we intend to begin enrollment for a Phase 3 clinical trial in the United States, Canada and Europe. As we expect to study only treatment naïve subjects in any Phase 3 clinical trial, we will need to seek participation of additional patients in that trial. We will need to activate new clinical study sites and enroll patients at forecasted rates at both new and existing clinical study 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 commencing our planned Phase 3 clinical trial. 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 planned Phase 3 clinical trial could be impaired and the costs of conducting the study could increase, either of which could have a material adverse effect on our business.

If clinical studies of VRS-317 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 positive

results, we may incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of VRS-317 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 VRS-317 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 VRS-317 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.

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.

VRS-317 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, VRS-317, 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 VRS-317 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 VRS-317 have reported certain adverse effects, such as mild and transient injection site discomfort, headaches and sore extremities, consistent with known adverse effects of rhGH therapy. No serious side effects have been reported to date. However, we cannot assure you that side effects from VRS-317 in current or future clinical trials will continue to be mild or that side effects in general will not prompt the discontinued development of VRS-317 or any future product candidates. As a result of these side effects or further safety or toxicity issues that we may experience in our clinical trials in the future, we may not receive approval to market VRS-317 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. 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 VRS-317 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 VRS-317 for growth in pediatric GHD patients based on a weekly, semi-monthly or monthly dosing regimen, the FDA or similar regulatory authorities outside the United States may not approve VRS-317 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 VRS-317 in the United States, Europe and Canada for treatment of pediatric GHD patients based on weekly, semi-monthly or monthly dosing regimens. It is possible that the FDA, the EMA or Health Canada may not consider the results of our clinical trials to be sufficient for approval of VRS-317 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 planned Phase 3 clinical trial, and considering that VRS-317 is a new chemical 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 VRS-317 for treatment of pediatric GHD patients based on weekly, semi-monthly or monthly dosing regimens, the approval may include additional restrictions on the label that could make VRS-317 less attractive to physicians and patients compared to other products that may be approved for broader indications, which could limit potential sales of VRS-317.

If we fail to obtain FDA or other regulatory approval of VRS-317 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 VRS-317 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 VRS-317 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 VRS-317 even if it is able to offer less frequent dosing. If VRS-317 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.

VRS-317 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 VRS-317, we must also design, manufacture, and gain regulatory approval of a delivery device to safely, effectively and conveniently administer VRS-317 in relevant patient types.

VRS-317 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 VRS-317, 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. For example, on February 20, 2014 the FDA notified us that it would require additional information before allowing us to use a newly manufactured lot of VRS-317 produced by our new manufacturer that we intend to use in our ongoing extension trial after our current supply of VRS-317 runs out. The FDA subsequently issued correspondence known as a partial clinical hold related exclusively to the use of any material produced by this new manufacturer, and requested additional information regarding the long-term stability of VRS-317 at 25°C and other information prior to allowing us to use the newly manufactured lot. We responded to the FDA's requests, and ultimately, after a second round of correspondence, we received a response from the FDA on June 11, 2014 notifying us that the partial clinical hold had been lifted. However, prior to commencing any future clinical trials, including our planned Phase 3 clinical trial, we must produce a lot of VRS-317 specifically for that trial.

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.VRS-317 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. VRS-317 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. We have entered into an agreement with a new third-party manufacturer 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 VRS-317, in order to successfully commercialize VRS-317, we will need to manufacture quantities of VRS-317 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 VRS-317 is higher than we anticipate or the obtainable sales price is lower than we anticipate, we may not be able to successfully commercialize VRS-317.

To commercialize VRS-317, we must design, manufacture, and gain regulatory approval of a delivery device to safely, effectively and conveniently administer VRS-317. We have engaged third-party manufacturers to design a suitable prototype for commercial purposes. There can be no assurances that these efforts will be successful. If we are unsuccessful in developing a suitable delivery device, our commercialization efforts would be impaired, which would

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, VRS-317, 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 VRS-317 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 VRS-317 is approved, we intend to commercialize it with our own specialty sales force in the United States, Canada 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 VRS-317, 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, VRS-317, for treatment of pediatric GHD patients based on a weekly, semi-monthly or 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), Tev-tropin® (Teva 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 VRS-317 to their current treatment regimens for a variety of potential reasons, including concerns about incurring potential additional costs related to VRS-317, the perception that the use of VRS-317 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. (via Prolor acquisition) 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 VRS-317 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 VRS-317 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 VRS-317 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 VRS-317 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 $5 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, VRS-317. 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 September 30, 2014, we had an accumulated deficit of $95.6 million.

To date, we have financed our operations primarily through private placements of our convertible preferred stock and the initial public offering of our common stock. 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, VRS-317, and any future product candidates;
- continue clinical studies of VRS-317, including the Phase 3 clinical trial of VRS-317 that we expect to initiate, which will be our most expensive clinical trial to date;
- seek to discover or in-license additional product candidates;
- seek regulatory approvals for VRS-317 and any future product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize VRS-317 or other future product candidates if they obtain regulatory approval, including process improvements in order to manufacture VRS-317 at commercial scale; and
- enhance operational, financial and information management systems and hire more personnel, including personnel to support development of VRS-317 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 VRS-317 as well as other products with significant market potential. This will require us to be successful in a range of activities, including advancing VRS-317 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 VRS-317 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 VRS-317 or any product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenue from product sales from VRS-317 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 study and planned Phase 3 clinical trials of VRS-317, successfully and on a timely basis;
- demonstrate the safety and efficacy of VRS-317 to the satisfaction of FDA and obtain regulatory approval for VRS-317 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 VRS-317 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 VRS-317 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 VRS-317 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, including, after the closing of this offering, 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 VRS-317 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 VRS-317 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 VRS-317 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 VRS-317 or any of our future product candidates;
- the level of demand for VRS-317 and any future product candidates, should they receive approval, which may fluctuate significantly and be difficult to predict;

- the risk/benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- competition from existing and potential future drugs that compete with VRS-317 or any of our future product candidates;
- our ability to commercialize VRS-317 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 VRS-317 and any future product candidates, should they receive approval, will require substantial funds. As of September 30, 2014, we had approximately $181.6 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 VRS-317 on a larger scale;
- the costs of commercialization activities if VRS-317 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 VRS-317 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 of VRS-317. 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 study. 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 VRS-317. 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 VRS-317. The manufacture of pharmaceutical products in compliance with the

FDA's cGMPs 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 requirements, other federal and state regulatory requirements and foreign regulations. If our manufacturer were to encounter any of these difficulties or otherwise fail to comply with its 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. For example, on February 20, 2014 the FDA notified us that it would require additional information before allowing us to use a newly manufactured lot of VRS-317 produced by our new manufacturer that we intend to use in our ongoing extension trial after our current supply of VRS-317 runs out. The FDA subsequently issued correspondence known as a partial clinical hold related exclusively to the use of any material produced by this new manufacturer, and requested additional information regarding the long-term stability of VRS-317 at 25°C and other information prior to allowing us to use the newly manufactured lot. We responded to the FDA's requests, and ultimately, after a second round of correspondence, we received a response from the FDA on June 11, 2014 notifying us that the partial clinical hold had been lifted. However, prior to commencing any future clinical trials, including our planned Phase 3 clinical trial, we must produce a lot of VRS-317 specifically for that trial.

All manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA through its 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 cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign 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, VRS-317, is a biologic and therefore requires a complex production process. In October, 2012, we transferred production of VRS-317 to a new manufacturer, Boehringer Ingelheim. In connection with the transfer of production, we are making certain changes to the manufacturing process in order to increase its scale and efficiency. We cannot assure you that we will be able to successfully implement this transition or implement the proposed improvements to the manufacturing process. If we are not able to implement the proposed transition in a timely manner or obtain the anticipated improvements in efficiency, our business, results of operations and growth prospects would be materially adversely affected. 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 VRS-317 until a qualified alternative manufacturer is identified, which could also delay the development of, and impair our ability to commercialize, VRS-317.

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 VRS-317 or any other product candidate may place the development of VRS-317 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 VRS-317 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. 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 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 October 31, 2014, we had 25 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;

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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) the last day of the fiscal year (a) following March 21, 2019 (the fifth anniversary of our initial public offering), (b) in which we have total annual gross revenue of at least $1.0 billion or (c) 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 (2) 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 VRS-317 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.

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 VRS-317, 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 VRS-317 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 VRS-317 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 VRS-317 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 VRS-317 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 licensers may become involved in proceedings, including oppositions, interferences, derivation proceedings inter partes reviews, patent nullification proceedings, or re-examinations, challenging our patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain. For example, Novo Nordisk A/S and XL-protein GmbH filed oppositions to an issued European patent relating to the XTEN technology. An adverse 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 VRS-317 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.

For example, on February 20, 2014 the FDA notified us that it would require additional information before allowing us to use a newly manufactured lot of VRS-317 produced by our new manufacturer that we intend to use in our ongoing extension trial after our current supply of VRS-317 runs out. We responded to the FDA's request, and ultimately, after a second round of correspondence, we received a response from the FDA on June 11, 2014 notifying us that the partial clinical hold had been lifted. However, prior to commencing any future clinical trials, including our planned Phase 3 clinical trial, we must qualify a source of VRS-317 specific to that trial. 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 VRS-317 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 VRS-317 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 VRS-317 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 VRS-317 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 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 PPACA, was enacted in 2010. The PPACA 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 PPACA, 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 PPACA 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 PPACA. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or its entirety. We cannot assure you that the PPACA, 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 PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by the sequestration

provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare reductions went into effect. We cannot predict whether any additional legislative changes will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

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

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

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

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

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

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
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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 PPACA, 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 PPACA 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. 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 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 VRS-317 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.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of October 31, 2014, we had outstanding 24,194,808 outstanding shares of common stock. 17,264,465 of these shares are currently restricted as a result of securities laws or lock-up agreements. Moreover, holders of 16,007,154 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once those shares are registered, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements.

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.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock beneficially own shares representing approximately 53.5% of our common stock as of October 31, 2014. 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote 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 will be 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 will 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 as early as our annual report on Form 10-K for the fiscal year ended December 31, 2014. 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. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. 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 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.

We have 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 financial statements. If we fail to remediate one or more of our material weaknesses 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 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 financial statements will not be prevented or detected on a timely basis.

Prior to the completion of our IPO, 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 IPO, 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.

For a discussion of our remediation plan and the actions that we have executed during 2013, see “Item 4—Controls and Procedures” included in Part I of this Quarterly Report on Form 10-Q. The actions we have taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. While we have implemented a plan to remediate this weakness we cannot assure you that we will be able to remediate this weakness, 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 remediate this material weakness, and if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with applicable NASDAQ listing requirements.

Our failure to remediate the material weakness identified above or the identification of additional material weaknesses in the future, could adversely affect our ability to report financial information, including our filing of quarterly or annual reports with the SEC on a timely and accurate basis. Moreover, our failure to remediate the material weakness identified above or the identification of additional material weaknesses, could prohibit us from producing timely and accurate consolidated financial statements, which may adversely affect our stock price and we may be unable to maintain compliance with 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 an active market for our common stock does not develop, 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 will be 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 will have 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 will prevent stockholders from being able to fill vacancies on our board of directors;

- our stockholders will not be 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 would not be 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 will prohibit cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- our stockholders will be 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 will be 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 that contain change in control and severance provisions providing for aggregate cash payments of up to approximately $2.0 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately $11.0 million (assuming a transaction and termination date of September 30, 2014 and based on the closing price of our common stock as of October 31, 2014), 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.

Cautionary statement concerning forward-looking statements

This quarterly report, including the sections titled "Risk factors" and "Management's discussion and analysis of financial condition and results of operations" contains forward-looking statements. In some cases you can identify these statements by forward-looking words, such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "project," "plan," "potential," "seek," "expect," "goal," or the negative or plural of these words or similar expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our expected uses of the net proceeds to us from our March 2014 offering;
- our ability to enroll patients in our clinical studies at the pace that we project;
- the timing and the success of the design of the Phase 2a stage of our Phase 1b/2a clinical trial and planned Phase 3 clinical trial of VRS-317;
- whether the results of our trials will be sufficient to support domestic or global regulatory approvals for VRS-317;
- our ability to obtain and maintain regulatory approval of VRS-317 or our future product candidates;
- our expectation that our existing capital resources and the net proceeds from our March 2014 offering will be sufficient to enable us to complete our planned Phase 3 clinical trial of VRS-317;
- the benefits of the use of VRS-317;

- our ability to successfully commercialize VRS-317 or any future product candidates;
- the rate and degree of market acceptance of VRS-317 or any future product candidates;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to manufacture VRS-317 in conformity with the FDA's requirements and to scale up manufacturing of VRS-317 to commercial scale;
- our ability to successfully build a specialty sales force and commercial infrastructure;
- our ability to compete with companies currently producing rhGH therapies;
- our reliance on third parties to conduct our clinical studies;
- our reliance on third-party contract manufacturers to manufacture and supply our product candidates for us;
- our reliance on our collaboration partners' performance over which we do not have control;
- our ability to retain and recruit key personnel, including development of a sales and marketing function;
- our ability to obtain and maintain intellectual property protection for VRS-317 or any future product candidates;
- the actual receipt and timing of any milestone payments or royalties from our collaborators;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act;
- our ability to identify, develop, acquire and in-license new products and product candidates;
- our ability to successfully establish and successfully maintain appropriate collaborations and derive significant revenue from those collaborations;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described above under the caption "Risk factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this report and the documents that we reference in this report and have filed with the SEC with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

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

Use of Proceeds

On March 26, 2014, we completed our IPO and issued 6,900,000 shares of our common stock, including the underwriter's exercise of their over-allotment option, at an initial offering price to the public of $21.00. We received net proceeds from the IPO of approximately $132.1 million, after deducting underwriting discounts and commissions of approximately $10.1 million and expenses of approximately $2.6 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. Principal underwriters were Morgan Stanley & Co. LLC and Citigroup Global Markets Inc.

Shares of our common stock began trading on the NASDAQ Global Select Market on March 21, 2014. The shares were registered under the Securities Act on registration statement on Form S-1 (Registration No. 333-193997).

We expect to continue to use the proceeds from the IPO to fund clinical trials of VRS-317 for the treatment of pediatric GHD, and for working capital and general corporate purposes. There has been no material change in the planned use of proceeds from our IPO as described in our prospectus dated March 21, 2014, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation by Reference Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Versartis, Inc.	8-K	001-36361	3.1	03/26/2014
3.2	Amended and Restated Bylaws of Versartis, Inc.	S-1/A	333-193997	3.4	03/06/2014
4.1	Form of Stock Certificate	10-Q	001-36361	4.1	05/14/2014
10.3	Form of 2014 Equity Incentive Plan Stock Option Grant Notice and Stock Option Agreement	S-8	333-194949	99.5	04/01/2014
10.4	Form of 2014 Equity Incentive Plan Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement	8-K	001-36361	10.1	04/17/2014
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: November 7, 2014 /s/ Jeffrey L. Cleland
Jeffrey L. Cleland

Chief Executive Officer

(Principal Executive Officer)

Date: November 7, 2014 /s/ Joshua T. Brumm
Joshua T. Brumm

Chief Financial Officer

(Principal Financial and Accounting Officer)