Viking Therapeutics, Inc.
Form 10-Q
June 12, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

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 001-37355

VIKING THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	2834	46-1073877
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

4370 La Jolla Village Drive, Suite 400

San Diego, California **92122**
(Address of Principal Executive Offices) **(Zip Code)**

11119 North Torrey Pines Road, Suite 50

San Diego, California 92037

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ¨ No x

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that 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:

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

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date:

Class	Number of Shares Outstanding

	as of June 10, 2015
Common stock, $0.00001 par value	9,783,312

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VIKING THERAPEUTICS, INC.

FORM 10-Q FOR THE THREE MONTHS ENDED MARCH 31, 2015

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Viking Therapeutics, Inc.

Balance Sheets

	March 31, 2015	December 31, 2014
	(Unaudited)	
Assets		
Current assets:		
Cash	$ 327,007	$ 755,857
Prepaid expenses and other current assets	33,391	17,827
Total current assets	360,398	773,684
Deferred IPO financing costs	2,408,149	2,268,675
Other assets	775	775
Total assets	$ 2,769,322	$ 3,043,134
Liabilities, convertible notes and stockholders deficit		
Current liabilities:		
Accounts payable	$ 1,879,414	$ 1,830,724
Accrued license fees	24,826,374	19,865,863
Other accrued liabilities	517,892	380,257
Accrued interest	112,475	77,222
Convertible notes payable, current portion (net of discount of $0 and $6,076 at March 31, 2015 and December 31, 2014, respectively)	310,350	304,274
Debt conversion feature liability	62,191	58,742
Total current liabilities	27,708,696	22,517,082
Convertible notes payable (net of discount of $1,070,007 and $1,235,886 at March 31, 2015 and December 31, 2014, respectively)	1,429,993	1,264,114
Debt conversion feature liability	1,469,676	1,390,469
Total long-term liabilities	2,899,669	2,654,583
Total liabilities	30,608,365	25,171,665
Commitments and Contingencies (See Note 4)		
Stockholders deficit:		
Common stock, $0.00001 par value: 25,000,000 shares authorized at March 31, 2015 and December 31, 2014; 6,000,000 shares issued and outstanding at March 31, 2015 and December 31, 2014	60	60

Additional paid-in capital	13,769	12,866
Accumulated deficit	(27,852,872)	(22,141,457)
Total stockholders deficit	(27,839,043)	(22,128,531)
Total liabilities and stockholders deficit	$ 2,769,322	$ 3,043,134

See accompanying notes to the financial statements.

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Viking Therapeutics, Inc.

Statements of Operations

(Unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Revenues	$	$
Operating expenses:		
Research and development	138,969	50,000
General and administrative	322,071	159,737
Total operating expenses	461,040	209,737
Loss from operations	(461,040)	(209,737)
Other expenses:		
Change in fair value of accrued license fees	4,960,511	
Change in fair value of debt conversion feature liability	82,656	10,249
Amortization of debt discount	171,955	6,379
Interest expense	35,253	2,576
Total other expenses	5,250,375	19,204
Net loss	(5,711,415)	(228,941)
Basic and diluted net loss per share	$ (1.40)	$ (0.08)
Weighted-average shares used to compute basic and diluted net loss per share	4,073,609	2,758,333

See accompanying notes to the financial statements.

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Viking Therapeutics, Inc.

Statements of Cash Flows

(Unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Cash flows from operating activities		
Net loss	$ (5,711,415)	$ (228,941)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of discount charged to interest expense on convertible notes	171,955	6,379
Change in fair value of accrued license fees	4,960,511	
Change in fair value of debt conversion feature liability	82,656	10,249
Stock-based compensation	903	904
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(15,564)	(7,500)
Accounts payable	37,306	115,565
Accrued expenses	62,707	2,576
Net cash used in operating activities	(410,941)	(100,768)
Cash flows from financing activities		
Repurchase of common stock		(2)
Deferred IPO financing costs paid	(17,909)	
Net cash provided by (used in) financing activities	(17,909)	(2)
Net increase (decrease) in cash	(428,850)	(100,770)
Cash, beginning of period	755,857	179,619
Cash, end of period	$ 327,007	$ 78,849
Supplemental disclosure of non-cash investing and financing transactions		
Repurchase of common stock		(1,998)
Deferred IPO costs included in accounts payable and accrued expenses	$ 2,057,903	$ 189,593

See accompanying notes to the financial statements.

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Viking Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

1. Organization, Liquidity and Management s Plan, and Summary of Significant Accounting Policies

The Company

Viking Therapeutics, Inc., a Delaware corporation (the Company), is a clinical-stage biopharmaceutical company focused on the development of novel, first-in-class or best-in-class therapies for metabolic and endocrine disorders.

The Company was incorporated under the laws of the State of Delaware on September 24, 2012 and its principal executive offices are located in San Diego, CA.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The accompanying balance sheet as of March 31, 2015, statements of operations for the three months ended March 31, 2015 and 2014 and cash flows for the three months ended March 31, 2015 and 2014 are unaudited. These unaudited financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These financial statements should be read in conjunction with the audited financial statements and the accompanying notes for the year ended December 31, 2014 contained in the final prospectus filed by the Company with the SEC on April 29, 2015 relating to the initial public offering (the IPO). The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company s financial position as of March 31, 2015 and the results of operations for the three months ended March 31, 2015 and 2014 and cash flows for the three months ended March 31, 2015 and 2014. The December 31, 2014 balance sheet included herein was derived from the audited financial statements, but does not include all disclosures or notes required by GAAP for complete financial statements.

The financial data and other information disclosed in these notes to the financial statements related to the three months ended March 31, 2015 and 2014 are unaudited. Interim results are not necessarily indicative of results for an entire year.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the accompanying financial statements. Significant estimates made in preparing these financial statements relate to determining the fair value of the debt conversion feature liability and accounting for certain commitments. Actual results could differ from those estimates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk principally consist of cash. The Company maintains its cash balances at what it believes are high credit-quality financial institutions. At times, balances at a single financial institution may exceed federally insured limits of $250,000.

Liquidity and Management s Plan

As of March 31, 2015, the Company did not have sufficient working capital to fund its planned operations without additional financing. In May 2015, the Company completed the IPO, issuing 3,450,000 shares of its common stock and raising $25,392,500 in net proceeds, including the full exercise of the over-allotment option, and after deducting underwriting discounts, commissions and a non-accountable expense in an aggregate amount of $2,207,500, but before deducting other offering costs and expenses. These additional funds raised in May 2015 alleviate any doubt in regards to the Company s ability to continue as a going concern. (See Note 5 regarding proceeds from the Company s initial public offering received in May 2015.)

Deferred IPO Financing Costs

Deferred IPO financing costs represent legal, accounting and other direct costs related to the Company s efforts to raise capital through a public sale of the Company s common stock. Costs related to the IPO were deferred until the completion of the IPO, at which time they were reclassified to additional paid-in capital as a reduction of the IPO proceeds. The IPO closed on May 4, 2015, at which time $2,408,149 of offering costs that were deferred at March 31, 2015 were recorded as a reduction of the proceeds received.

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Revenue Recognition

The Company has not recorded any revenues since its inception. However, in the future the Company may enter into collaborative research and licensing agreements, under which the Company could be eligible for payments made in the form of upfront license fees, research funding, cost reimbursement, contingent event-based payments and royalties.

Revenue from upfront, nonrefundable license fees is to be recognized over the period that any related services are to be provided by the Company. Amounts received for research funding are to be recognized as revenue as the research services that are the subject of such funding are performed. Revenue derived from reimbursement of research and development costs in transactions where the Company acts as a principal are to be recorded as revenue for the gross amount of the reimbursement, and the costs associated with these reimbursements are to be reflected as a component of research and development expense in the statements of operations.

Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 605-28, *Revenue Recognition Milestone Method* (ASC 605-28), established the milestone method as an acceptable method of revenue recognition for certain contingent event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event (1) that can be achieved based in whole or in part on either the Company s performance or on the occurrence of a specific outcome resulting from the Company s performance, (2) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (3) that would result in additional payments being due to the Company. The determination that a milestone is substantive is judgmental and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is (a) commensurate with either the Company s performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from the Company s performance to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all deliverables and payment terms in the arrangement.

Other contingent event-based payments received for which payment is either contingent solely upon the passage of time or the results of a collaborative partner s performance are not considered milestones under ASC 605-28. In accordance with ASC Topic 605-25, *Revenue Recognition Multiple-Element Arrangements* (ASC 605-25), such payments will be recognized as revenue when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, price is fixed or determinable and collectability is reasonably assured. Revenues recognized for royalty payments, if any, are based upon actual net sales of the licensed compounds, as provided by the collaboration arrangement, in the period the sales occur. Any amounts received prior to satisfying the Company s revenue recognition criteria are recorded as deferred revenue on its balance sheets.

Research and Development Expenses

The Company s historical research and development expenses have primarily related to obtaining the option to license compounds and related intellectual property rights from Ligand Pharmaceuticals Incorporated (Ligand). In May 2014, the Company entered into a master license agreement with Ligand, as amended (the Master License Agreement), pursuant to which it acquired certain rights to a number of research and development programs from Ligand. In doing so, the Company has since updated its policy on research and development to include the purchase of rights to intangible assets. In accordance with ASC Topic 730, *Research and Development*, intangible assets that are acquired and have an alternative future use, as defined, should be capitalized and reported as an intangible asset; however, the

cost of acquired intangible assets that do not have alternative future uses should be reported as research and development expense as incurred. The Company notes that intangible assets acquired that are in the preclinical or clinical stages of development when acquired, and not approved by the U.S. Food and Drug Administration, are deemed to have not satisfied the definition of having an alternative future use, as defined. Accordingly, assets acquired in the preclinical and clinical stages of development should be expensed as incurred in the Company s statement of operations.

All costs of research and development are expensed in the period incurred. Research and development costs primarily consist of fees paid to clinical research organizations (CROs) and clinical trial sites, employee and consultant related expenses, which include salaries, benefits and stock-based compensation for research and development personnel, external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations, facilities costs, travel costs, dues and subscriptions, depreciation and materials used in preclinical studies, clinical trials and research and development.

The Company estimates its preclinical study and clinical trial expenses based on the services it received pursuant to contracts with research institutions and CROs that conduct and manage preclinical studies and clinical trials on the Company s behalf. Clinical trial-related contracts vary significantly in length, and may be for a fixed amount, based on milestones or deliverables, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. The Company accrues service fees based on work performed, which relies on estimates of total costs incurred based on milestones achieved, patient enrollment and other events. The majority of the Company s service providers invoice the Company in arrears, and to the extent that amounts invoiced differ from its estimates of expenses incurred, the Company accrues for additional costs. The financial terms of these agreements vary from contract to contract and may result in uneven expenses and payment flows. Preclinical study and clinical trial expenses include:

fees paid to CROs, consultants and laboratories in connection with preclinical studies;

fees paid to CROs, clinical trial sites, investigators and consultants in connection with clinical trials; and

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fees paid to contract manufacturers and service providers in connection with the production, testing and packaging of active pharmaceutical ingredients and drug materials for preclinical studies and clinical trials.

Payments under some of these agreements depend on factors such as the milestones accomplished, including enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. To date, the Company has not experienced any events requiring it to make material adjustments to its accruals for service fees. If the Company does not identify costs that it has begun to incur or if it underestimates or overestimates the level of services performed or the costs of these services, its actual expenses could differ from its estimates, which could materially affect its results of operations. Adjustments to the Company s accruals are recorded as changes in estimates become evident. Furthermore, based on amounts invoiced to the Company by its service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as services are rendered.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred to General and administrative expense, as recoverability of such expenditures is uncertain.

Stock-Based Compensation

The Company has accounted for stock-based compensation by measuring and recognizing compensation expense for all share-based payments made to employees and directors based on estimated award date fair values. These estimates are highly complex and subjective in nature. With the Company becoming a publicly traded company in April 2015, these valuations and estimates are no longer necessary as the Company will rely on the market price to determine market value for the Company s common stock. The Company uses the straight-line method to allocate compensation cost to reporting periods over each restricted award s requisite service period, which is generally the vesting period, and has estimated the fair value of restricted stock-based awards to employees and consultants using a Monte Carlo market approach simulation method and performed an allocation of value to common stock based on the estimated time to a liquidity event. In addition, the Company accounts for performance-based restricted stock awards to employees by determining the fair value of the restricted stock award at the date of issuance by using the Probability Weighted Expected Return Method (PWERM) and then assessing at each balance sheet date the probability of the performance criteria being met. If the probability of achieving the criteria is deemed less-than-probable, then no expense is recorded. At the point where the criteria are deemed probable of being met, then the Company begins recording stock-based compensation with a cumulative catch-up expense in the period first recognized and then on a straight-line basis over the remaining period for which the performance criteria are expected to be completed.

As of March 31, 2015, the Company did not have a formal stock option plan. In connection with the IPO (See Note 5), the Viking Therapeutics, Inc. 2014 Equity Incentive Plan (the 2014 Plan) and the Viking Therapeutics, Inc. 2014 Employee Stock Purchase Plan (the 2014 Purchase Plan) became effective on April 28, 2015, the date of the execution and delivery of the underwriting agreement for the IPO.

The Company will use the straight-line method to allocate compensation cost to reporting periods over each optionee s requisite service period, which is generally the vesting period, and will estimate the fair value of share-based awards or restricted stock units to employees and directors using the Black-Scholes option-valuation model. The Black-Scholes model requires the input of subjective assumptions, including volatility, the expected term and the fair value of the underlying common stock on the date of grant, among other inputs. Stock options granted to non-employees are accounted for using the fair value approach. Stock options granted to non-employees are subject to periodic revaluation over their vesting terms.

2014 Plan. The 2014 Plan provides that the compensation committee of the Company s Board of Directors (the Compensation Committee) may grant or issue stock options, stock appreciation rights, restricted shares, restricted stock units and unrestricted shares, deferred share units, performance and cash-settled awards and dividend equivalent rights to participants under the 2014 Plan. Initially, a total of 1,527,770 shares of the Company s common stock have been reserved for issuance pursuant to the 2014 Plan, which number is also the limit on shares of common stock available for awards of incentive stock options. The number of shares available for issuance under the 2014 Plan will, unless otherwise determined by the Company s Board of Directors or the Compensation Committee, be automatically increased on January 1st of each year commencing on January 1, 2016 and ending on (and including) January 1, 2024, in an amount equal to 3.5% of the total number of shares of the Company s common stock outstanding on December 31st of the preceding calendar year. The shares of common stock deliverable pursuant to awards under the 2014 Plan will be authorized but unissued shares of the Company s common stock, or shares of the Company s common stock that the Company otherwise holds in treasury or in trust. Any shares of the Company s common stock underlying awards that are settled in cash or otherwise expire, or are forfeited, terminated or cancelled (including pursuant to an exchange program established by the Compensation Committee) prior to the issuance of stock will again be available for issuance under the 2014 Plan. In addition, shares of the Company s common stock that are withheld (or not issued) in payment of the exercise price or taxes relating to an award, and shares of the Company s common stock equal to the number surrendered in payment of any exercise price or withholding taxes relating to an award, will again be available for issuance under the 2014 Plan.

2014 Purchase Plan. Initially, a total of 458,331 shares of the Company s common stock have been reserved for issuance pursuant to the 2014 Purchase Plan. The number of shares available for issuance under the 2014 Purchase Plan will, unless otherwise determined by the Company s Board of Directors or the Compensation Committee, be automatically increased on January 1st of each year commencing on January 1, 2016 and ending on (and including) January 1, 2024, in an amount equal to 1% of the total number of shares of the Company s common stock

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outstanding on December 31st of the preceding calendar year. The shares of common stock available for purchase pursuant to the 2014 Purchase Plan will be authorized but unissued shares of the Company s common stock, shares of the Company s common stock that the Company otherwise holds in treasury or shares of the Company s common stock that were purchased on the open market in arms length transactions in accordance with applicable securities laws. Shares of the Company s common stock will be offered for purchase under the 2014 Purchase Plan as determined by the Compensation Committee through a series of successive offerings that each have a term of 24 months and consist of four consecutive purchase periods of six months each. Prior to the commencement of any future offering under the 2014 Purchase Plan, the Compensation Committee may determine that the current offering shall end, may commence a new offering on the first day after the end of such terminal purchase period (or any desired later date), and may decide that future offerings will consist of one or more consecutive purchase periods, each to be of such duration as determined by the Compensation Committee; however, no offering will exceed 27 months and no purchase period will exceed one year. Each employee of the Company who (1) is an employee on the first date of any offering under the 2014 Purchase Plan, (2) is customarily scheduled to work for more than 20 hours per week and more than five months per calendar year, and (3) meets such other criteria as may be determined by the Compensation Committee (consistent with Section 423 of the Internal Revenue Code of 1986, as amended), is eligible to participate in the 2014 Purchase Plan for each purchase period within such offering. The purchase price per share of the Company s common stock under the 2014 Purchase Plan may not be less than, and will initially be equal to, the lesser of: (1) 85% of the fair market value per share of the Company s common stock on the first day of the offering, or (2) 85% of the fair market value per share of the Company s common stock on the date the purchase right is exercised, which will be the last day of the applicable purchase period.

Income Taxes

The Company accounts for its income taxes using the liability method whereby deferred tax assets and liabilities are determined based on temporary differences between the basis used for financial reporting and income tax reporting purposes. Deferred income taxes are provided based on the enacted tax rates in effect at the time such temporary differences are expected to reverse. A valuation allowance is provided for deferred tax assets if it is more likely than not that the Company will not realize those tax assets through future operations.

Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. Income tax positions that previously failed to meet the more-likely-than-not threshold are recognized in the first subsequent financial reporting period in which that threshold is met. Previously recognized tax positions that no longer meet the more-likely-than-not threshold are derecognized in the first subsequent financial reporting period in which that threshold is no longer met.

Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, the Company currently does not have any deemed common share equivalents; therefore, its basic and diluted net loss per share calculations are the same.

The following table presents the computation of basic and diluted net loss per common share:

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Historical net loss per share		
Numerator		
Net loss attributable to common stockholders	$ (5,711,415)	$ (228,941)
Denominator		
Weighted-average common shares outstanding	6,000,000	5,433,333
Less: Weighted-average shares subject to repurchase	(1,926,391)	(2,675,000)
Denominator for basic and diluted net loss per share	4,073,609	2,758,333
Basic and diluted net loss per share	$ (1.40)	$ (0.08)

Potentially dilutive securities that are not included in the calculation of diluted net loss per share because their effect is anti-dilutive are as follows (in common equivalent shares):

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Common stock subject to repurchase	1,741,670	2,912,500

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Segments

The Company operates in only one segment. Management uses cash flows as the primary measure to manage its business and does not segment its business for internal reporting or decision making.

2. Fair Value of Financial Instruments

The Company s financial instruments consist of cash, accounts payable, accrued license fees, debt and its related debt conversion feature liability. The carrying amounts reported in the accompanying balance sheets for cash and accounts payable approximate fair value because of the short-term maturity of those instruments. The Company s accrued license fees have been recorded based on Level 3 fair value inputs, which consist of unobservable inputs and generally reflect management s estimate of assumptions that market participants would use in pricing the assets. The Company s convertible notes are convertible into capital stock, and the related debt conversion feature has been recorded as a liability also based on Level 3 fair value inputs. The fair value of the debt conversion feature liability required management to make assumptions about the probability of the occurrence of a capital stock issuance by the Company resulting in net proceeds of at least $5,000,000 and the convertible notes being converted based on the applicable conversion terms. Alternate probabilities would have resulted in increases or decreases in the fair value of the debt conversion feature liability. The Company did not have any assets or liabilities categorized as Level 1 or Level 2 in the fair value hierarchy as of March 31, 2015 or March 31, 2014. There have been no changes in the methodologies used at March 31, 2015 or March 31, 2014.

The fair values of the Company s financial instruments measured using Level 3 unobservable inputs are presented below:

	March 31, 2015	March 31, 2014
Liabilities		
Accrued license fees (Level 3)	$ 24,826,374	$
Debt conversion feature current (Level 3)	62,191	
Debt conversion feature long-term (Level 3)	1,469,676	81,904
Total Liabilities Measured at Fair Value	$ 26,358,241	$ 81,904

The table below presents a summary of changes in the Company s accrued license fees and debt conversion feature liability measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three months ended March 31, 2015 and 2014:

	Accrued License Fees	Debt Conversion Feature Liability
Balance at December 31, 2013	$	$ 71,655
Additions		
		10,249

Adjustments Resulting from Changes In Fair Value Recognized in Earnings		
Balance at March 31, 2014		81,904
Balance at December 31, 2014	19,865,863	1,449,211
Additions		
Adjustments Resulting from Changes In Fair Value Recognized in Earnings	4,960,511	82,656
Balance at March 31, 2015	$ 24,826,374	$ 1,531,867

The following table sets forth the Company s valuation techniques and significant unobservable inputs used to determine fair value for significant Level 3 liabilities:

	Fair Value			Significant Unobservable Input	Range
	Assets	Liabilities	Valuation Technique(s)		
Accrued license fees					
March 31, 2015	$	$ 24,826,374	Probability weighted expected return model	Discount rates	12% to 60%
Debt conversion feature liability					
March 31, 2015		1,531,867	Discounted cash flow model	Timing of the events	3/31/2015 - 6/30/2015
				Probabilities of Occurrence	30% to 40% for each
				Discount rate	37.5%
March 31, 2014		81,904	Discounted cash flow model	Timing of the events	6/30/2014 to 1/1/2016
				Probabilities of Occurrence	35% to 60%
				Discount rate	40.0%

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Level 3 Fair Value Sensitivity

Accrued license fees

For accrued license fees, generally increases (decreases) in the probability weightings assigned to each scenario would result in increases (decreases) to the fair value. In general, an increase (decrease) in discount rate tends to result in (decreases) increases to fair value.

Debt conversion feature liability

The fair value of the debt conversion feature liability includes the estimated timing of the events as well as the related probabilities of occurrence. The shorter/longer the period estimated to the event, the higher/lower the value of the debt conversion feature liability. The higher/lower the probability of occurrence, the higher/lower the value of the debt conversion feature liability.

3. Stockholders Deficit

In February 2014, the Company entered into a stock purchase agreement with one of its founders. The agreement provided for the purchase of 1,000,000 shares of the Company s common stock at a price per share of $0.01 in exchange for future services to be rendered to the Company as measured by certain performance criteria. The shares are subject to a repurchase option and vest in two tranches of 500,000 shares each, upon achievement of the performance target or upon a triggering event as defined.

To appropriately account for this stock purchase, the Company determined the fair value of the common stock on the date of purchase as well as the likelihood of achievement of each of the performance conditions included in the agreement. The valuation methodology utilized in determining fair value relied on the PWERM, which incorporates relevant events and expected future exit scenarios for the Company. The exit scenarios included merger and acquisition and initial public offering scenarios. The enterprise value under each scenario was based primarily on the market approach and probability-weighted expected exit values for the Company under each scenario. Similar merger and acquisition transactions and publicly traded companies were utilized within the market approach and appropriate metrics were applied to the Company along with qualitative comparable assessments. The indicated value under the market approach was used as the starting aggregate value for the valuation of these performance-based shares. The Company utilized a Monte Carlo simulation method to determine the fair value of the performance-based shares as of the issuance date. The Monte Carlo simulation method takes into consideration the expected timing of the performance milestones, probability of achieving the milestones and estimated per share common stock prices at expected vesting dates.

The Company determined that the issuance in February 2014 had a deemed fair value lower than the reassessed fair value of the common stock on the date of issuance based upon the PWERM. Since the stock issuance to the founder is tied to certain performance criteria, the Company reviewed the probability of achieving such criteria at February 20, 2014, March 31, 2014 and March 31, 2015 and determined that it was not probable that the criteria would be met. Therefore, no compensation expense has been recorded for this issuance through March 31, 2015. The Company will continue to reassess at each reporting period whether it is probable that either of the two performance criteria will be met, and if and when either are deemed probable, the Company will begin to record compensation expense using the fair value to determine stock-based compensation expense in its financial statements over the period the Company estimates the performance criteria will actually be met. The Company determined that the fair value of the unrecognized expense was $168,000 at February 20, 2014, the grant date.

There were no new stock issuances during the three months ended March 31, 2015.

Stock-based compensation expense includes restricted stock awards issued to employees and non-employees and has been reported in the Company s statements of operations as follows:

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Research and development	$	$
General and administrative	903	904
Total	$ 903	$ 904

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At March 31, 2015 and March 31, 2014, there were 1,741,670 and 2,912,500 unvested shares of common stock, respectively, and $170,367 and $174,127, respectively, of total unrecognized compensation cost related to the issuance of the 6,000,000 shares of common stock outstanding, which is expected to be recognized over a weighted-average period of 1.35 years and 0.93 years, respectively.

4. Commitments and Contingencies

In March 2014, the Company paid $50,000 to extend an option to potentially enter into a license agreement to develop and commercialize products through March 29, 2015. In order to exercise the option, the Company would have needed to deliver to Ligand, the licensor, a notice of exercise accompanied by a $1,000,000 payment. Alternatively, the Company could have delivered a notice of exercise accompanied by a $500,000 payment and 10% of the gross amount the Company received in any financing resulting in at least $1,000,000 in gross proceeds to the Company. The maximum amount due to the licensor if the Company had elected to exercise the option via the alternative payment method was $1,500,000. In May 2014, the Company entered into the Master License Agreement with Ligand that included a license to the products covered by the option.

5. Subsequent Events

The Company has evaluated all subsequent events through the filing date of this Quarterly Report on Form 10-Q with the SEC, to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of March 31, 2015, and events which occurred subsequently but were not recognized in the financial statements. Except as described below, there were no other subsequent events which required recognition, adjustment to or disclosure in the financial statements.

On April 8, 2015, the Company entered into a Second Amendment to Master License Agreement with Ligand, pursuant to which the parties agreed to revise (1) the calculations used to determine the number of securities to be issued to Ligand upon the closing of the IPO, and (2) certain of the royalty percentages payable by the Company to Ligand based on worldwide annual net sales of the products licensed under the Master License Agreement.

Further, on April 8, 2015, the Company and Ligand entered into a First Amendment to Loan and Security Agreement with Ligand (the Loan Amendment), pursuant to which the parties agreed to amend, among other things, the timing of Ligand s conversion rights under the Secured Convertible Promissory Note issued to Ligand on May 21, 2014 (the Ligand Note) following certain Company transactions. Under the terms of the Loan Amendment, following the consummation of the earlier to occur of (1) a bona fide capital financing transaction or series of financing transactions with one or more financial non-strategic investors resulting in aggregate net proceeds to the Company of at least $20,000,000 and pursuant to which the Company issues shares of its equity securities, (2) a firmly underwritten public offering pursuant to the Securities Act of 1933, as amended (the Securities Act), on Form S-1 or Form S-3, or any successor forms, or (3) May 4, 2016 (the one year anniversary of the closing of the IPO), Ligand may elect to convert the Ligand Note into shares of the Company s common stock and/or cash in an amount equal to 200% of the principal amount of the loan plus all accrued and previously unpaid interest thereon. Additionally, pursuant to the Loan Amendment, Ligand has agreed that it will not, until the earlier of (A) 270 days from the date of conversion of the Ligand Note or (B) April 28, 2016 (one year following the date of the prospectus filed with the SEC relating to the IPO), sell or otherwise transfer or dispose of the shares of common stock issuable upon conversion of the Ligand Note.

On May 4, 2015, the Company completed the IPO pursuant to a Registration Statement on Form S-1 that was declared effective on April 28, 2015. In the IPO, the Company sold 3,000,000 shares of its common stock at an initial public offering price of $8.00 per share. The underwriters for the IPO had 30 days to exercise an over-allotment option to

purchase up to an additional 450,000 shares at the initial public offering price, less the underwriting discount. Upon the closing of the IPO, on May 4, 2015, the Company raised a total of $22,080,500 in net proceeds after deducting underwriting discounts, commissions and a non-accountable expense allowance in an aggregate amount of $1,919,500, but before deducting other offering costs and expenses. Costs directly associated with the IPO of approximately $3,000,000 were capitalized and recorded as deferred IPO costs prior to the closing of the IPO. These costs have been recorded as a reduction of the proceeds received in arriving at the amount to be recorded in additional paid-in capital upon completion of the IPO.

On May 4, 2015, prior to the completion of the IPO, the Company repurchased an aggregate of 3,802,859 shares of its common stock from its stockholders at a price of $0.00001 per share for an aggregate purchase price of $38. Pursuant to the Master License Agreement, upon the closing of the IPO, on May 4, 2015, the Company issued an aggregate of 3,427,859 shares of its common stock to Ligand and Metabasis Therapeutics, Inc., a wholly-owned subsidiary of Ligand (Metabasis).

On May 26, 2015, the underwriters for the IPO exercised in full their over-allotment option to purchase an additional 450,000 shares of the Company s common stock at $8.00 per share, less the underwriting discount. On May 28, 2015, the Company sold the 450,000 shares to the underwriters pursuant to the over-allotment option and received additional net proceeds of $3,312,000, after deducting underwriting discounts and commissions, but before deducting other offering costs and expenses. Upon the closing of the over-allotment option, pursuant to the Master License Agreement, on May 28, 2015, the Company issued an additional aggregate of 228,105 shares of its common stock to Ligand and Metabasis.

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The following unaudited pro forma balance sheet information as of March 31, 2015 assumes that the IPO had been consummated as of March 31, 2015. The unaudited pro forma balance sheet information as of March 31, 2015 gives effect to: (a) the conversion of $24,826,374 of accrued license fees as of March 31, 2015 into 3,655,964 shares of the Company s common stock pursuant to the Master License Agreement, based upon 5,625,000 shares of common stock deemed to be outstanding as of immediately prior to the closing of the IPO under the Master License Agreement (after giving effect to the Company s repurchase of an aggregate of 3,802,859 shares of its common stock from its stockholders effected prior to the completion of the IPO), based on the IPO offering price of $8.00 per share; (b) a non-cash interest charge of $4,421,338 at the time of conversion of the accrued license fees, relating to the difference between the carrying amounts of the $24,826,374 of accrued license fees and the fair market value of the shares issued in the IPO, based on the IPO offering price of $8.00 per share; (c) the conversion of $310,350 of the Company s convertible notes payable plus interest of $22,614 as of March 31, 2015 into 56,764 shares of the Company s common stock; (d) a beneficial conversion charge of $121,181; (e) the issuance of an aggregate of 472,565 shares of the Company s common stock and grants of options to purchase an aggregate of 206,000 shares of the Company s common stock to its employees, directors and a consultant of the Company upon the consummation of the IPO pursuant to employment agreements, offer letters and a consulting agreement, based on the IPO offering price of $8.00 per share (for certain of the restricted stock issued and stock options granted to employees that were fully vested on the grant date, the Company would have recorded stock compensation expense of $1,040,032, based upon a Black Scholes value of $4.36, calculated using the IPO offering price of $8.00 per share, a volatility of 85.2%, a 3 year term, an interest rate of 0.89% and zero dividends); and (f) the Company s repurchase of 3,802,859 shares of its common stock from its stockholders effected prior to the completion of the IPO, based on the IPO offering price of $8.00 per share.

The following table summarizes certain actual balance sheet data and pro forma balance sheet data to reflect the activities related to the IPO, as of March 31, 2015:

	March 31, 2015	Pro forma March 31, 2015
Cash and cash equivalents	$ 327,007	$ 25,719,469
Deferred IPO costs	2,408,149	
Accounts payable	1,879,414	1,850,654
Accrued license fees	24,826,374	
Accrued interest	112,475	89,861
Convertible notes payable, current	310,350	
Debt conversion feature liability	62,191	
Common stock	60	98
Additional paid in capital	13,769	53,768,693
Accumulated deficit	(27,852,872)	(33,373,232)
Total stockholders equity (deficit)	$ (27,839,043)	$ 20,395,559

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

This Quarterly Report on Form 10-Q contains forward-looking statements as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, in connection with the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties, as well as

assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially and adversely from those expressed or implied by such forward-looking statements. Such forward-looking statements include estimates of our expenses, future revenue, capital requirements and our needs for additional financing; statements regarding our ability to develop, acquire, and advance drug candidates into, and successfully complete, clinical trials and preclinical studies; statements concerning new product candidates; risks and uncertainties associated with our research and development activities, including our clinical trials and preclinical studies; our expectations regarding the potential market size and the size of the patient populations for our drug candidates, if approved for commercial use, and our ability to serve such markets; statements regarding our ability to maintain and establish collaborations or obtain additional funding; statements regarding developments and projections relating to our competitors and our industry and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. These statements are often identified by the use of words such as anticipate, believe, continue, could, estimate, expect, intend, may or will, the negative versions of these terms and similar expressions or variations. 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 factors that could cause actual results and the timing of certain events to differ materially and adversely 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 elsewhere in this Quarterly Report on Form 10-Q and in our other Securities and Exchange Commission (SEC) filings. Furthermore, such forward-looking statements speak only as of the date of this report. We undertake no obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of such statements.

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Overview

We are a clinical-stage biopharmaceutical company focused on the development of novel, first-in-class or best-in-class therapies for metabolic and endocrine disorders. We have exclusive worldwide rights to a portfolio of five drug candidates in clinical trials or preclinical studies, which are based on small molecules licensed from Ligand. Our lead clinical program is VK5211, an orally available drug candidate entering a Phase 2 clinical trial for acute rehabilitation following non-elective hip fracture surgery. Hip fracture is a common injury among persons aged 60 and older. The acute recovery period post-injury is characterized by significant and rapid declines in bone mineral density, or BMD, and lean body mass, or LBM, which contributes to substantial morbidity and mortality in these patients. VK5211 is a non-steroidal selective androgen receptor modulator, or SARM. A SARM is designed to selectively interact with a subset of receptors that have a normal physiologic role of interacting with naturally-occurring hormones called androgens. Broad activation of androgen receptors with drugs, such as exogenous testosterone, can stimulate muscle growth and improve BMD, but often results in unwanted side effects such as prostate growth, hair growth and acne. VK5211 is expected to selectively produce the therapeutic benefits of testosterone in muscle and bone tissue, potentially accelerating rehabilitation and improving patient outcomes. VK5211 is also expected to have improved safety, tolerability and patient acceptance relative to testosterone. We expect to commence the Phase 2 study of VK5211 in 2015 and to complete the trial in the first half of 2016.

Our second clinical program is focused on two lead compounds, VK2809 and VK0214, for adrenoleukodystrophy, or ALD, a rare X-linked, inherited, neurological disorder characterized by a breakdown in the protective barriers surrounding brain and nerve cells. The disease, for which there is no approved treatment, is caused by mutations in a peroxisomal transporter of very long chain fatty acids, or VLCFA, known as ABCD1. As a result, transporter function is impaired and patients are unable to efficiently metabolize VLCFA. VK2809 and VK0214 are novel selective thyroid hormone receptor beta, or TRß, agonists. The thyroid beta receptor is known to regulate expression of an alternative VLCFA transporter, known as ABCD2. Various preclinical models have demonstrated that increased expression of ABCD2 can lead to normalization of VLCFA metabolism. Preclinical studies are ongoing through our collaboration with the Academic Medical Center, at the University of Amsterdam. Preliminary data suggest that our molecules stimulate ABCD2 expression levels. Pending completion of this work, we expect to initiate clinical studies in late 2015 or early 2016, and report preliminary results in 2016. We also plan to explore the potential for our thyroid beta agonist program to treat hypercholesterolemia and fatty liver disease. Our most advanced TRß molecule, VK2809, has demonstrated excellent preliminary efficacy in a clinical study of hypercholesterolemia.

We were incorporated under the laws of the State of Delaware on September 24, 2012. Since our incorporation, we have devoted substantially all of our efforts to raising capital, building infrastructure and obtaining the worldwide rights to certain technology, including VK5211, VK2809 and VK0214, pursuant to an exclusive license agreement with Ligand. The terms of this license agreement are detailed in the Master License Agreement, or the Master License Agreement, with Ligand Pharmaceuticals Incorporated, or Ligand, which we entered into on May 21, 2014. A summary of the Master License Agreement, as amended, can be found in the section entitled Business-Agreements with Ligand Master License Agreement of the final prospectus, dated April 28, 2015, that we filed with the Securities and Exchange Commission on April 29, 2015.

On May 4, 2015, we completed our initial public offering of our common stock, or the IPO, pursuant to a Registration Statement on Form S-1 that was declared effective on April 28, 2015. In the IPO, we sold 3,000,000 shares of our common stock at an initial public offering price of $8.00 per share. The underwriters for the IPO had 30 days to exercise an over-allotment option to purchase up to an additional 450,000 shares at the initial public offering price, less the underwriting discount. Upon the closing of the IPO, on May 4, 2015, we raised a total of $22,080,500 in net proceeds after deducting underwriting discounts, commissions and a non-accountable expense allowance in an aggregate amount of $1,919,500, but before deducting other offering costs and expenses.

On May 26, 2015, the underwriters of the IPO exercised in full their over-allotment option to purchase an additional 450,000 shares of our common stock. On May 28, 2015, we sold the 450,000 shares to the underwriters pursuant to the over-allotment option and received additional net proceeds of $3,312,000, after deducting underwriting discounts and commissions, but before deducting other offering costs and expenses.

Although it is difficult to predict our liquidity requirements, based upon our current operating plan, and the proceeds received from the IPO, we believe we will have sufficient cash to meet our projected operating requirements for at least the next 12 months.

As of March 31, 2015, we had an accumulated deficit of $27,852,872. These losses have resulted principally from research and development costs incurred in connection with acquiring the exclusive worldwide rights to the portfolio of five drug candidates discussed above and the related non-cash interest expense recorded for increases in the deemed fair market value for the license fees payable to Ligand, consulting fees and general and administrative expenses, including planning for the continued clinical development of VK5211, VK2809 and VK0214. We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development of our clinical drug candidates and preclinical programs and incur additional costs associated with being a public company.

Financial Operations Overview

Revenues

To date, we have not generated any revenue. We do not expect to receive any revenue from any drug candidates that we develop unless and until we obtain regulatory approval for, and commercialize, such drug candidates or enter into collaborative agreements with third parties.

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Research and Development Expenses

We had limited operating expenses related to research and development activities through May 2014. In May 2014, we acquired certain rights to a number of research and development programs from Ligand and charged $21,687,576 to research and development expense during the year ended December 31, 2014 as a cost of acquiring these assets. We expect that our ongoing research and development expenses will consist of costs incurred for the development of our drug candidates, and include:

- expenses incurred under agreements with investigative sites and contract research organizations, or CROs, which will conduct a substantial portion of our research and development activities on our behalf;
- employee and consultant-related expenses, which will include salaries, benefits and stock-based compensation, and certain consultant fees and travel expenses;
- payments to third-party manufacturers, which will produce our active pharmaceutical ingredients and finished products;
- license fees paid to third parties for use of their intellectual property; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements and equipment and laboratory and other supplies.

We expense all research and development costs as incurred.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming and the successful development of our drug candidates is highly uncertain. Our future research and development expenses will depend on the clinical success of each of our drug candidates, as well as ongoing assessments of the commercial potential of such drug candidates. In addition, we cannot forecast with any degree of certainty which drug candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We expect to incur increased research and development expenses as we commence our Phase 2 clinical trial for VK5211, advance VK2809 and/or VK0214 into clinical trials and seek to advance our additional programs.

General and Administrative Expenses

To date, general and administrative expenses have consisted primarily of salaries and related benefits paid to our employees in executive, operational and finance functions, including stock compensation and fees paid to certain consultants to help commence and continue our operations. We expect that our general and administrative expenses will increase in the future in order to support our research and development activities, including increased salaries and other related costs, stock-based compensation and consulting fees for executive, finance, accounting and business development functions. Other significant costs are expected to include legal fees relating to patent and corporate matters, facility costs not otherwise included in research and development expenses, and fees for accounting and other

consulting services. We also expect general and administrative expenses to increase as we are now a public company, including expenses related to compliance with the rules and regulations of the SEC and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administration and professional services.

Other Expenses

Other expenses include the change in fair value of the debt conversion feature liability contained in our outstanding convertible promissory notes issued from September 2012 through June 2013, or the Convertible Notes, the Secured Convertible Promissory Note issued to Ligand on May 21, 2014, or the Ligand Note, and the change in fair value at each reporting period of the accrued license fees set up on May 21, 2014, which accounts for non-cash other expense associated with the increase in fair value of the debt conversion feature liability and accrued license fees and interest expense, which consists primarily of interest accrued on the Convertible Notes and the Ligand Note, and non-cash interest related to the amortization of debt discount costs associated with the Convertible Notes and the Ligand Note.

JOBS Act

We are an emerging growth company within the meaning of the rules under the Securities Act of 1933, as amended, or the Securities Act, and we will utilize certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies. For example, as an emerging growth company, we will not be required to provide an auditor s attestation report on our internal control over financial reporting in future annual reports on Form 10-K as otherwise required by Section 404(b) of the Sarbanes-Oxley Act. In addition, Section 107 of the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, provides that an emerging growth company can utilize the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to opt out of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act. As a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

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Critical Accounting Policies and Estimates

Our management s discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to preclinical, nonclinical and clinical development costs and drug manufacturing costs. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 1 to our financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations

Comparison of the Three Months Ended March 31, 2015 and 2014

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2015 and 2014.

	Three Months Ended March 31,		$ Change	% Change
	2015	2014		
Research and development expenses	$ 138,969	$ 50,000	$ 88,969	177.9%

During the three months ended March 31, 2015, we incurred minimal research and development expenses as we were primarily focused on our fund raising efforts related to the IPO. We did, however, expense $82,000 related to salaries and wages and related taxes and certain healthcare benefits, $34,000 related to certain preclinical efforts for our thyroid Beta program and $12,000 for certain drug substance efforts primarily for our SARM program. During the three months ended March 31, 2014, we expensed a $50,000 payment made to Ligand to extend our option to license certain technology from Ligand, prior to entering into the Master License Agreement.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2015 and 2014.

	Three Months Ended March 31,		$ Change	% Change
	2015	2014		

General and administrative expenses	$ 322,071	$ 159,737	$ 162,334	101.6%

The increase in general and administrative expenses was primarily due to an increase in salaries and wages, including stock-based compensation expense of $101,000 during the three months ended March 31, 2015 as compared to the three months ended March 31, 2014. The increase also reflects $14,000 in additional accounting costs and audit fees, $10,000 in additional consulting expenses, $12,000 in additional patent related costs, $12,000 in additional insurance premiums expense and $8,000 in additional rent for the three months ended March 31, 2015 as compared to the three months ended March 31, 2014.

Other expenses

The following table summarizes our other expenses for the three months ended March 31, 2015 and 2014.

	Three Months Ended March 31,		$ Change	% Change
	2015	2014		
Other expenses	$ 5,250,375	$ 19,204	$ 5,231,171	27,240.0%

Other expenses increased during the three months ended March 31, 2015 primarily due to the establishment in May 2014 of a license fee liability in accordance with the Master License Agreement entered into with Ligand on May 21, 2014, which requires the license fee liability to be marked to market at each reporting period. The increase in other expenses for the three months ended March 31, 2015 as compared to the three months ended March 31, 2014 is primarily due to the recording of an increase in the value of the license fee liability of $4,961,000 during the three months ended March 31, 2015. This license fee liability was not in place as of March 31, 2014. In addition, during the three months ended March 31, 2015, there were additional amounts recorded to other expenses related to the Ligand Note that also did not exist at March 31, 2014. During the three months ended March 31, 2015, we recorded $166,000 related to the amortization of the Ligand Note discount, $31,000 related to interest expense on the Ligand Note and $79,000 related to the change in fair value of the Ligand Note s conversion feature.

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Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations and have not generated any revenues since our inception. As of March 31, 2015, we did not have sufficient capital to fund our planned operations without additional financing. In May 2015, we completed the IPO (as discussed below) and we now believe we will have sufficient cash to meet our projected operating requirements for at least the next 12 months.

Our primary use of cash is to fund operating expenses, which to date has consisted of the cost to obtain the license of intellectual property from Ligand, and certain research and development and general and administrative expenses. Since we have not generated any revenues, we have incurred operating losses since our inception. Cash used to fund operating expenses is impacted by the timing of payment of these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Subsequent to March 31, 2015, we completed the following transactions:

On May 4, 2015, we completed the IPO. In the IPO, we sold 3,000,000 shares of our common stock at an initial public offering price of $8.00 per share. The underwriters for the IPO had 30 days to exercise an over-allotment option to purchase up to an additional 450,000 shares at the initial public offering price, less the underwriting discount. Upon the closing of the IPO, on May 4, 2015, we raised a total of $22,080,500 in net proceeds after deducting underwriting discounts and commissions of $1,919,500. Costs directly associated with the IPO were capitalized and recorded as deferred IPO costs prior to the closing of the IPO. These costs have been recorded as a reduction of the proceeds received in arriving at the amount to be recorded in additional paid-in capital.

On May 4, 2015, prior to the completion of the IPO, we repurchased an aggregate of 3,802,859 shares of our common stock from our stockholders at a price of $0.00001 per share for an aggregate purchase price of $38. Pursuant to the Master License Agreement, upon the closing of the IPO, on May 4, 2015, we issued an aggregate of 3,427,859 shares of our common stock to Ligand and Metabasis Therapeutics, Inc., a wholly-owned subsidiary of Ligand, or Metabasis.

On May 26, 2015, the underwriters of the IPO exercised in full their over-allotment option to purchase an additional 450,000 shares of our common stock at $8.00 per share, less the underwriting discount. On May 28, 2015, we sold the 450,000 shares to the underwriters pursuant to the over-allotment option and received additional net proceeds of $3,312,000, after deducting underwriting discounts and commissions, but before deducting other offering costs and expenses. Upon the closing of the over-allotment option, pursuant to the Master License Agreement, on May 28, 2015, we issued an additional aggregate of 228,105 shares of our common stock to Ligand and Metabasis.

The following table summarizes our cash flows for the periods indicated below:

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Cash used in operating activities	$ (410,941)	$ (100,768)
Cash used in investing activities	$	$
Cash used in financing activities	$ (17,909)	$ (2)

Cash Used in Operating Activities

During the three months ended March 31, 2015, cash used in operating activities was $410,941. Cash used in operating activities primarily reflected our net losses for the period, offset by non-cash charges such as an increase in the fair value of accrued license fees and debt conversion feature liability, amortization of discount charged to interest expense on Convertible Notes and the Ligand Note, stock compensation and changes in our working capital accounts, primarily an increase in prepaid expenses, accounts payable and accrued expenses.

During the three months ended March 31, 2014, cash used in operating activities was $100,768. Cash used in operating activities primarily reflected our net losses for the period, offset by non-cash charges such as changes in fair value of debt conversion feature liability, amortization of discount charged to interest expense on the Convertible Notes and stock compensation, as well as changes in our working capital accounts, primarily an increase in prepaid expenses, accounts payable and accrued expenses.

Cash Used in Investing Activities

We have not engaged in any investing activities since our inception.

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Cash Used in Financing Activities

During the three months ended March 31, 2015, cash used in financing activities was $17,909, which consisted of payments of certain deferred IPO financing costs.

During the three months ended March 31, 2014, cash used in financing activities was $2, which consisted of the repurchase of shares of restricted common stock at par value.

Future Funding Requirements

Based upon our current operating plan, and with the offering proceeds received in May 2015 from our IPO, we believe we will have sufficient cash to meet our projected operating requirements for at least the next 12 months.

We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase materially as we continue the development of, and seek regulatory approvals for, our drug candidates, and seek to commercialize any drugs for which we receive regulatory approval. We anticipate that we will need to raise additional capital to fund our operations and complete our ongoing and planned clinical trials. Although we expect to finance future cash needs through public or private equity or debt offerings, funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, preclinical studies and other related activities;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future drug candidates;
- the number and characteristics of the drug candidates we seek to develop or commercialize;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our drug candidates;
- the cost of commercialization activities if any of our current or future drug candidates are approved for sale, including marketing, sales and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;

our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;

the amount of revenue, if any, received from commercial sales of our drug candidates, should any of our drug candidates receive marketing approval; and

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of March 31, 2015, we had cash totaling $327,007, consisting of bank deposits. These cash balances are not subject to significant interest rate risk and the carrying value of our cash approximated its fair value. As of March 31, 2015, we also held convertible notes payable which carry variable interest rates and the interest payments are therefore subject to interest rate risk, while the principal is not subject to interest rate risk. If the applicable federal rate were to change by 1%, thereby changing our effective borrowing rate by the same amount, interest expense related to the convertible notes payable would change by approximately $776 in the next three months, until their expected maturity. Consequently, our results of operations and cash flows are not subject to significant interest rate risk related to these convertible notes payable.

We do not have any foreign currency or derivative financial instruments accounted for under hedge accounting.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q at the reasonable assurance level.

Changes in Internal Control

There has been no change in our internal control over financial reporting during the three months ended March 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently party to, and none of our property is currently the subject of, any material legal proceedings.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, before making a decision to invest in our common stock. The risks and uncertainties described below may not be the only ones we face. If any of the risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment.

Risks Relating to Our Business

We are a clinical-stage company, have a very limited operating history and are expected to incur significant operating losses during the early stage of our corporate development.

We are a clinical-stage company. We were incorporated in, and have only been conducting operations since, September 2012. Our operations to date have been limited to raising capital, building infrastructure, obtaining the worldwide rights to certain technology from Ligand Pharmaceuticals Incorporated, or Ligand, and planning and preparing for preclinical studies and clinical trials of our drug candidates, including VK5211, which has completed Phase 1 clinical development, VK2809, VK0214 and VK0612, which is currently in Phase 2 clinical development, and the EPOR and DGAT-1 programs, which are currently in preclinical development. As a result, we have no meaningful historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to obtain marketing approval for any of our drug candidates or successfully overcome the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry. We also have not generated any

revenue to date, and we continue to incur significant research and development and other expenses. Our net loss for the three months ended March 31, 2015 and 2014 was $5,711,415 and $228,941, respectively. As of March 31, 2015, we had an accumulated deficit of $27,852,872. For the foreseeable future, we expect to continue to incur losses, which will increase significantly from historical levels as we expand our drug development activities, seek regulatory approvals for our drug candidates and begin to commercialize them if they are approved by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or comparable foreign authorities. Even if we succeed in developing and commercializing one or more drug candidates, we may never become profitable. If we fail to achieve or maintain profitability, it would adversely affect the value of our common stock.

We are substantially dependent on technologies we in-license from Ligand, and if we lose the right to license such technologies or the Master License Agreement is terminated for any reason, our ability to develop existing and new drug candidates would be harmed, and our business, financial condition and results of operations would be materially and adversely affected.

Our business is substantially dependent upon technology licensed from Ligand. Pursuant to the Master License Agreement, we have been granted exclusive worldwide rights to VK5211, VK2809, VK0214, VK0612 and preclinical programs for anemia and lipid disorders. SARMS, such as our lead program VK5211, are key compounds used by us in the development and commercialization of our drug candidates. All of the intellectual property related to our drug candidates is currently owned by Ligand, and we have the rights to use such intellectual property pursuant to the Master License Agreement. Therefore, our ability to develop and commercialize our drug candidates depends entirely on the effectiveness and continuation of the Master License Agreement. If we lose the right to license any of these key compounds, our ability to develop existing and new drug candidates would be harmed.

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Ligand has the right to terminate the Master License Agreement under certain circumstances, including, but not limited to: (1) in the event of our insolvency or bankruptcy, (2) if we do not pay an undisputed amount owing under the Master License Agreement when due and fail to cure such default within a specified period of time, or (3) if we default on certain of our material obligations and fail to cure the default within a specified period of time.

We are dependent on the success of one or more of our current drug candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized.

We have spent significant time, money and effort on the development of our core metabolic and endocrine disease assets, VK5211, VK2809, VK0214, VK0612 and our earlier-stage assets, the EPOR and DGAT-1 programs. To date, no pivotal clinical trials designed to provide clinically and statistically significant proof of efficacy, or to provide sufficient evidence of safety to justify approval, have been completed with any of our drug candidates. All of our drug candidates will require additional development, including clinical trials as well as further preclinical studies to evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation, and regulatory clearances before they can be commercialized. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory clearances will be obtained. Our drug development efforts may not lead to commercial drugs, either because our drug candidates fail to be safe and effective or because we have inadequate financial or other resources to advance our drug candidates through the clinical development and approval processes. If any of our drug candidates fail to demonstrate safety or efficacy at any time or during any phase of development, we would experience potentially significant delays in, or be required to abandon, development of the drug candidate.

We do not anticipate that any of our current drug candidates will be eligible to receive regulatory approval from the FDA, EMA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for any of these drug candidates, we or our potential future partners, if any, may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost-effectiveness, the cost of manufacturing the product on a commercial scale and competition with other drugs. The success of our drug candidates may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current drug candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our financial condition and stock price may decline.

If development of our drug candidates does not produce favorable results, we and our collaborators, if any, may be unable to commercialize these products.

To receive regulatory approval for the commercialization of our core metabolic and endocrine disease assets, VK5211, VK2809, VK0214, VK0612 and our earlier-stage assets, the EPOR and DGAT-1 programs, or any other drug candidates that we may develop, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA, EMA and comparable foreign authorities. In order to support marketing approval, these agencies typically require successful results in one or more Phase 3 clinical trials, which our current drug candidates have not yet reached and may never reach. The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent commercialization of our current or future drug candidates, including the following:

- clinical trials may produce negative or inconclusive results;

preclinical studies conducted with drug candidates during clinical development to, among other things, evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation may produce unfavorable results;

patient recruitment and enrollment in clinical trials may be slower than we anticipate;

costs of development may be greater than we anticipate;

our drug candidates may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance, if approved;

collaborators who may be responsible for the development of our drug candidates may not devote sufficient resources to these clinical trials or other preclinical studies of these candidates or conduct them in a timely manner; or

we may face delays in obtaining regulatory approvals to commence one or more clinical trials.

Success in early development does not mean that later development will be successful because, for example, drug candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical trials.

We in-license all of the intellectual property related to our drug candidates from Ligand pursuant to the Master License Agreement. All clinical trials, preclinical studies and other analyses performed to date with respect to our drug candidates have been conducted by Ligand. Therefore, as a company, we do not have any experience in conducting clinical trials for our drug candidates. Since our experience with our drug candidates is limited, we will need to train our existing personnel and hire additional personnel in order to successfully administer and manage our clinical trials and other studies as planned, which may result in delays in completing such planned clinical trials and preclinical studies.

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Moreover, to date our drug candidates have been tested in less than the number of patients that will likely need to be studied to obtain regulatory approval. The data collected from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these drug candidates.

We currently do not have strategic collaborations in place for clinical development of any of our current drug candidates. Therefore, in the future, we or any potential future collaborative partner will be responsible for establishing the targeted endpoints and goals for development of our drug candidates. These targeted endpoints and goals may be inadequate to demonstrate the safety and efficacy levels required for regulatory approvals. Even if we believe data collected during the development of our drug candidates are promising, such data may not be sufficient to support marketing approval by the FDA, EMA or comparable foreign authorities. Further, data generated during development can be interpreted in different ways, and the FDA, EMA or comparable foreign authorities may interpret such data in different ways than us or our collaborators. Our failure to adequately demonstrate the safety and efficacy of our drug candidates would prevent our receipt of regulatory approval, and ultimately the potential commercialization of these drug candidates.

Since we do not currently possess the resources necessary to independently develop and commercialize our drug candidates, including our core metabolic and endocrine disease assets, VK5211, VK2809, VK0214, VK0612 and our earlier-stage assets, the EPOR and DGAT-1 programs, or any other drug candidates that we may develop, we may seek to enter into collaborative agreements to assist in the development and potential future commercialization of some or all of these assets as a component of our strategic plan. However, our discussions with potential collaborators may not lead to the establishment of collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and potential commercialization delays, which would adversely affect our business, financial condition and results of operations.

We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability.

We expect to expend substantial funds in research and development, including preclinical studies and clinical trials of our drug candidates, and to manufacture and market any drug candidates in the event they are approved for commercial sale. We also may need additional funding to develop or acquire complementary companies, technologies and assets, as well as for working capital requirements and other operating and general corporate purposes. Moreover, our planned increases in staffing will dramatically increase our costs in the near and long-term.

Because the successful development of our drug candidates is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate sufficient revenue, even if we are able to commercialize any of our drug candidates, to become profitable.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

We are a clinical-stage company, and the development and commercialization of our drug candidates is uncertain and expected to require substantial expenditures. We have not yet generated any revenues from our operations to fund our activities, and are therefore dependent upon external sources for financing our operations. The audit report issued by our independent registered public accounting firm for our financial statements for the fiscal year ended December 31, 2013 states that our independent registered public accounting firm has substantial doubt in our ability to continue as a going concern. In addition, the audit report issued by our independent registered public accounting firm for our financial statements for the fiscal year ended December 31, 2014 states that our independent registered public accounting firm has substantial doubt in our ability to continue as a going concern due to the risk that we may not

have sufficient cash and liquid assets at December 31, 2014 to cover our operating and capital requirements for the next 12 months; and if in that case sufficient cash cannot be obtained, we would have to substantially alter, or possibly even discontinue, operations. As of March 31, 2015, we did not have sufficient capital to fund our planned operations without additional financing. However, as of June 11, 2015, based upon our current operating plan, and the proceeds received from the IPO in May 2015, we believe we will have sufficient cash to meet our projected operating requirements for at least the next 12 months.

Even after giving effect to our receipt of the net proceeds from the completion of our initial public offering in May 2015, we expect we will need to raise additional capital, which may be unavailable to us or, even if consummated, may cause dilution or place significant restrictions on our ability to operate our business.

Since we will be unable to generate sufficient, if any, cash flow to fund our operations for the foreseeable future, we may need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations. As of March 31, 2015, we had cash of $327,007.

There can be no assurance that we will be able to raise sufficient additional capital, if needed, on acceptable terms, or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations may be materially adversely affected. In addition, we may be required to grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves. Our inability to fund our business could lead to the loss of your investment.

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Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, preclinical studies and other related activities;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future drug candidates;
- the number and characteristics of the drug candidates we seek to develop or commercialize;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our drug candidates;
- the cost of commercialization activities if any of our current or future drug candidates are approved for sale, including marketing, sales and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the amount of revenue, if any, received from commercial sales of our drug candidates, should any of our drug candidates receive marketing approval; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

If we raise additional capital by issuing equity securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock. Given our need for cash and that equity issuances are the most common type of fundraising for companies like ours, the risk of dilution is particularly significant for stockholders of our company.

Our drug candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition and results of operations.

Undesirable side effects observed in clinical trials or in supportive preclinical studies with our drug candidates could interrupt, delay or halt their development and could result in the denial of regulatory approval by the FDA, EMA or comparable foreign authorities for any or all targeted indications or adversely affect the marketability of any such drug candidates that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our drug candidates.

We are aware of several previous SARM drug development programs. No SARM is currently being tested in patients who have undergone hip fracture surgery. The most advanced SARM in clinical development is GTx, Inc. s enobosarm, currently being evaluated for patients with a specific type of breast cancer. In two previous 20-week Phase 3 studies in cancer cachexia, patients receiving enobosarm demonstrated significant improvements in lean body mass. However, in one of the Phase 3 studies, patients receiving enobosarm did not demonstrate a statistically significant improvement in functional performance as measured by stair climbing power.

Our drug candidates may exhibit adverse effects in preclinical toxicology studies and adverse interactions with other drugs. There are also risks associated with additional requirements the FDA, EMA or comparable foreign authorities may impose for marketing approval with regard to a particular disease.

Our drug candidates may require a risk management program that could include patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post-marketing observational study, and ongoing safety and reporting mechanisms, among other requirements. Prescribing could be limited to physician specialists or physicians trained in the use of the drug, or could be limited to a more restricted patient population. Any risk management program required for approval of our drug candidates could potentially have an adverse effect on our business, financial condition and results of operations.

Undesirable side effects involving our drug candidates may have other significant adverse implications on our business, financial condition and results of operations. For example:

- we may be unable to obtain additional financing on acceptable terms, if at all;
- our collaborators may terminate any development agreements covering these drug candidates;
- if any development agreements are terminated, we may determine not to further develop the affected drug candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all;

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if we were to later continue the development of these drug candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their commercialization;

we may be subject to product liability or stockholder litigation; and

we may be unable to attract and retain key employees.

In addition, if any of our drug candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

regulatory authorities may withdraw their approval of the product, or we or our partners may decide to cease marketing and sale of the product voluntarily;

we may be required to change the way the product is administered, conduct additional clinical trials or preclinical studies regarding the product, change the labeling of the product, or change the product s manufacturing facilities; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

Our efforts to discover drug candidates beyond our current drug candidates may not succeed, and any drug candidates we recommend for clinical development may not actually begin clinical trials.

We intend to use our technology, including our licensed technology, knowledge and expertise to develop novel drugs to address some of the world s most widespread and costly chronic diseases. We intend to expand our existing pipeline of core assets by advancing drug compounds from current ongoing discovery programs into clinical development. However, the process of researching and discovering drug compounds is expensive, time-consuming and unpredictable. Data from our current preclinical programs may not support the clinical development of our lead compounds or other compounds from these programs, and we may not identify any additional drug compounds suitable for recommendation for clinical development. Moreover, any drug compounds we recommend for clinical development may not demonstrate, through preclinical studies, indications of safety and potential efficacy that would support advancement into clinical trials. Such findings would potentially impede our ability to maintain or expand our clinical development pipeline. Our ability to identify new drug compounds and advance them into clinical development also depends upon our ability to fund our research and development operations, and we cannot be certain that additional funding will be available on acceptable terms, or at all.

Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.

Delays in the commencement or completion of clinical trials could significantly impact our drug development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to:

- obtaining regulatory approval to commence one or more clinical trials;
- reaching agreement on acceptable terms with prospective third-party contract research organizations, or CROs, and clinical trial sites;
- manufacturing sufficient quantities of a drug candidate or other materials necessary to conduct clinical trials;
- obtaining institutional review board approval to conduct one or more clinical trials at a prospective site;
- recruiting and enrolling patients to participate in one or more clinical trials; and
- the failure of our collaborators to adequately resource our drug candidates due to their focus on other programs or as a result of general market conditions.

In addition, once a clinical trial has begun, it may be suspended or terminated by us, our collaborators, the institutional review boards or data safety monitoring boards charged with overseeing our clinical trials, the FDA, EMA or comparable foreign authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA, EMA or comparable foreign authorities resulting in the imposition of a clinical hold;

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unforeseen safety issues; or

lack of adequate funding to continue the clinical trial.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to commence product sales and generate product revenues from any of our product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Delays in completing our clinical trials could also allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

This drug candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early to late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve these intended objectives.

Any of these changes could make the results of our planned clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our product candidates, and/or jeopardize our ability to commence product sales and generate revenues.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians and patients perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Additionally, enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business, financial condition and results of operations could be substantially harmed.

Ligand, the licensor of our development programs, has relied upon and plans to continue to rely upon third-party CROs, medical institutions, clinical investigators and contract laboratories to monitor and manage data for our licensed ongoing preclinical and clinical programs. We have relied and expect to continue to rely on these parties for execution of our preclinical studies and clinical trials, and we control only certain aspects of their activities. Nevertheless, we maintain responsibility for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with current requirements on good manufacturing practices, or cGMP, good clinical practices, or GCP, and good laboratory practice, or GLP, which are a collection of laws and regulations enforced by the FDA, EMA or comparable foreign authorities for all of our drug candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fails to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign authorities

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may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes.

If any of our relationships with these third-party CROs, medical institutions, clinical investigators or contract laboratories terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our drug candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition or results of operations.

Our drug candidates are subject to extensive regulation under the FDA, EMA or comparable foreign authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our drug candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of our drug candidates are subject to extensive regulation by the FDA and other U.S. regulatory agencies, EMA or comparable authorities in foreign markets. In the U.S., neither we nor our collaborators are permitted to market our drug candidates until we or our collaborators receive approval of a new drug application, or an NDA, from the FDA or receive similar approvals abroad. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the drug candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at all. For example, the FDA has released draft guidance regarding clinical trials for drug candidates treating diabetes that may result in more stringent requirements for the clinical trials and regulatory approval of such drug candidates. This and any future guidance that may result from recent FDA advisory panel discussions may make it more expensive to develop and commercialize such drug candidates. Such increased expense could make it more difficult to obtain favorable terms in the collaborative arrangements we require to maximize the value of our programs seeking to develop new drug candidates for diabetes. In addition, as a company, we have not previously filed NDAs with the FDA or filed similar applications with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility.

Despite the time and expense invested, regulatory approval is never guaranteed. The FDA, EMA or comparable foreign authorities can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed safe or effective;
- agency officials of the FDA, EMA or comparable foreign authorities may not find the data from non-clinical or preclinical studies and clinical trials generated during development to be sufficient;
- the FDA, EMA or comparable foreign authorities may not approve our third-party manufacturers processes or facilities; or
- the FDA, EMA or a comparable foreign authority may change its approval policies or adopt new regulations.

Our inability to obtain these approvals would prevent us from commercializing our drug candidates.

Even if our drug candidates receive regulatory approval in the U.S., we may never receive approval or commercialize our products outside of the U.S.

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay seeking or obtaining such approval would impair our ability to develop foreign markets for our drug candidates.

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Even if any of our drug candidates receive regulatory approval, our drug candidates may still face future development and regulatory difficulties.

If any of our drug candidates receive regulatory approval, the FDA, EMA or comparable foreign authorities may still impose significant restrictions on the indicated uses or marketing of the drug candidates or impose ongoing requirements for potentially costly post-approval studies and trials. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer s facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, our collaborators or us, including requiring withdrawal of the product from the market. Our drug candidates will also be subject to ongoing FDA, EMA or comparable foreign authorities requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. If our drug candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or other notices of possible violations;
- impose civil or criminal penalties or fines or seek disgorgement of revenue or profits;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators;
- withdraw any regulatory approvals;
- impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing operations; or
- seize or detain products or require a product recall.

The FDA, EMA and comparable foreign authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA, EMA and comparable foreign authorities strictly regulate the promotional claims that may be made about prescription products, such as our drug candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, EMA or comparable foreign authorities as reflected in the product s approved labeling. If we receive marketing approval for our drug candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment that our products could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy

civil, criminal or administrative penalties, and seek fines against us. Such enforcement has become more common in the industry. The FDA, EMA or comparable foreign authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our drug candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition and results of operations.

If our competitors have drug candidates that are approved faster, marketed more effectively or demonstrated to be more effective than ours, our commercial opportunity may be reduced or eliminated.

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including commercial biopharmaceutical enterprises, academic institutions, government agencies and private and public research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than any which we are developing, or that would render our drug candidates obsolete and noncompetitive. Even if we obtain regulatory approval of any of our drug candidates, our competitors may succeed in obtaining regulatory approvals for their products earlier than we do. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

VK5211

The key competitive factors affecting the success of VK5211, if approved, are likely to be its efficacy, safety, tolerability, frequency and route of administration, convenience and price, the level of branded and generic competition and the availability of coverage and reimbursement from government and other third-party payors.

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In the U.S., there are currently no marketed therapies for the maintenance or improvement of lean body mass, or LBM, bone mineral density, or BMD, and function in patients recovering from non-elective hip fracture surgery. There are several experimental therapies in various stage of development for acute rehabilitation following hip fracture surgery, including programs in development at Novartis AG and Morphosys AG. There are also several experimental therapies that are in various stages of clinical development for conditions characterized by muscle wasting by companies including GTx, Inc., Helsinn Group and Morphosys AG. In addition, nutritional and growth hormone-based therapies are sometimes used in patients experiencing muscle wasting.

VK2809 and VK0214

The key competitive factors affecting the success of VK2809 and VK0214, if approved, are likely to be efficacy, safety, tolerability, frequency and route of administration, convenience and price, the level of branded and generic competition and the availability of coverage and reimbursement from government and other third-party payors.

In the U.S., there are currently no marketed therapies for the treatment of adrenoleukodystrophy. Hematopoietic stem cell therapy has been used to treat the most severe form of adrenoleukodystrophy, cerebral adrenoleukodystrophy, or CALD. More recently, gene therapy has been shown to be effective in CALD as well. However, both treatments are invasive, requiring surgical intervention, and these do not appear to have an effect on the most pervasive form of adrenoleukodystrophy, adrenomyeloneuropathy, or AMN. High-dose biotin is under investigation for treatment of AMN. There are several experimental therapies that are in various stages of clinical development for adrenoleukodystrophy by companies, including MedDay Pharmaceuticals and bluebird bio, Inc.

VK0612

The key competitive factors affecting the success of VK0612, if approved, are likely to be its efficacy, safety, tolerability, frequency and route of administration, convenience and price, and the level of branded and generic competition and the availability of coverage and reimbursement from government and other third-party payors.

In the U.S., there are a variety of currently marketed oral type 2 diabetes therapies, including metformin (generic), pioglitazone (generic), glimepiride (generic), sitagliptin (Merck & Co., Inc.) and canagliflozin (Johnson & Johnson). These therapies are well-established and are widely accepted by physicians, patients, caregivers and third-party payors as the standard of care for the treatment of type 2 diabetes. Physicians, patients and third-party payors may not accept the addition of VK0612 to their current treatment regimens for a variety of potential reasons, including:

- if they do not wish to incur any potential additional costs related to VK0612; or
- if they perceive the use of VK0612 to be of limited additional benefit to patients.

In addition to the currently approved and marketed type 2 diabetes therapies, there are a number of experimental drugs that are in various stages of clinical development by companies such as Eli Lilly and Company, Takeda Pharmaceutical Company Limited and TransTech Pharma, Inc.

Preclinical Programs Focused on EPOR Agonists and DGAT-1 Inhibitors

If any of our preclinical programs are ultimately determined safe and effective and approved for marketing, they may compete for market share with established therapies from a number of competitors, including large biopharmaceutical

companies. Many therapies are currently available and numerous others are being developed for the treatment of dyslipidemia, NASH, anemia and obesity. Any products that we may develop from our preclinical programs may not be able to compete effectively with existing or future therapies.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our drug candidates.

The process of manufacturing our drug candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our drug candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our drug candidates could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our drug candidates or in the manufacturing facilities in which our drug candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our drug candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

In addition, any adverse developments affecting manufacturing operations for our drug candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls, or other interruptions in the supply of our drug candidates. We also may need to take inventory write-offs and incur other charges and expenses for drug candidates that fail to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives.

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We rely completely on third parties to manufacture our preclinical and clinical drug supplies, and our business, financial condition and results of operations could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in our clinical trials, and we lack the resources and the capability to manufacture any of our drug candidates on a clinical or commercial scale. We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our drug candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs, and there may be a need to identify alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our drug candidates for our clinical trials, and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a drug candidate to complete such clinical trial, any significant delay or discontinuity in the supply of a drug candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our drug candidates, which could harm our business, financial condition and results of operations.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our drug candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our drug candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our drug candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA or marketing authorization application, or MAA, on a timely basis and must adhere to good laboratory practice and cGMP regulations enforced by the FDA, EMA or comparable foreign authorities through their facilities inspection program. Some of our contract manufacturers may not have produced a commercially approved pharmaceutical product and therefore may not have obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our drug candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our drug candidates or any of our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time

consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition and results of operations.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA, EMA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a drug candidate, withdrawal of an approval, or suspension of production. As a result, our business, financial condition and results of operations may be materially and adversely affected.

Additionally, if supply from one manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or MAA variation, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our drug candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Any collaboration arrangement that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future drug candidates.

We may seek collaboration arrangements with biopharmaceutical companies for the development or commercialization of our current and potential future drug candidates. To the extent that we decide to enter into collaboration agreements, we will face significant competition in

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seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement can lead to delays in developing or commercializing the applicable drug candidate and can be difficult to resolve in a mutually beneficial manner. In some cases, collaborations with biopharmaceutical companies and other third parties are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect our business, financial condition and results of operations.

If we are unable to enter into agreements with third parties to sell and market our drug candidates, we may be unable to generate significant revenues.

We do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. If any of our drug candidates are approved for commercialization, we may be required to develop our sales, marketing and distribution capabilities, or make arrangements with a third party to perform sales and marketing services. Developing a sales force for any resulting product or any product resulting from any of our other drug candidates is expensive and time consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our drug candidates. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenues are likely to be lower than if we marketed and sold our drug candidates independently. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

The commercial success of our drug candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community.

Even if our drug candidates obtain regulatory approval, our products, if any, may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any of our approved drug candidates will depend on a number of factors, including:

- the effectiveness of our approved drug candidates as compared to currently available products;
- patient willingness to adopt our approved drug candidates in place of current therapies;
- our ability to provide acceptable evidence of safety and efficacy;

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

restrictions on use in combination with other products;

availability of alternative treatments;

pricing and cost-effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our drug candidates and target markets;

effectiveness of our or our partners sales and marketing strategy;

our ability to obtain sufficient third-party coverage or reimbursement; and

potential product liability claims.

In addition, the potential market opportunity for our drug candidates is difficult to precisely estimate. Our estimates of the potential market opportunity for our drug candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. Independent sources have not verified all of our assumptions. If any of these assumptions proves to be inaccurate, then the actual market for our drug candidates could be smaller than our estimates of our potential market opportunity. If the actual market for our drug candidates is smaller than we expect, our product revenue may be limited, it may be harder than expected to raise funds and it may be more difficult for us to achieve or maintain profitability. If we fail to achieve market acceptance of our drug candidates in the U.S. and abroad, our revenue will be limited and it will be more difficult to achieve profitability.

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If we fail to obtain and sustain an adequate level of reimbursement for our potential products by third-party payors, potential future sales would be materially adversely affected.

There will be no viable commercial market for our drug candidates, if approved, without reimbursement from third-party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our current drug candidates or any other drug candidate we may develop. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U.S. healthcare industry toward cost containment.

Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. We believe our drugs will be priced significantly higher than existing generic drugs and consistent with current branded drugs. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payors may not be willing to provide reimbursement for our drugs, which would significantly reduce the likelihood of our products gaining market acceptance.

We expect that private insurers will consider the efficacy, cost-effectiveness, safety and tolerability of our potential products in determining whether to approve reimbursement for such products and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition and results of operations would be materially adversely affected if we do not receive approval for reimbursement of our potential products from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our drug candidates or other potential products.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can exceed 12 months. 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 products to other available therapies.

If the prices for our potential products are reduced or if governmental and other third-party payors do not provide adequate coverage and reimbursement of our drugs, our future revenue, cash flows and prospects for profitability will suffer.

Recently enacted and future legislation may increase the difficulty and cost of commercializing our drug candidates and may affect the prices we may obtain if our drug candidates are approved for commercialization.

In the U.S. and some foreign jurisdictions, there have been a number of adopted and proposed legislative and regulatory changes regarding the healthcare system that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-marketing activities and affect our ability to profitably sell any of our drug candidates for which we obtain regulatory approval.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the PPACA, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The PPACA increased manufacturers rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of average manufacturer price, or AMP, which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services, which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U.S., such as Puerto Rico and the Virgin Islands. Further, beginning in 2011, the PPACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a

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50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the donut hole. Although it is too early to determine the full effects of the PPACA, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been introduced at both the state and federal level to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing approval testing and other requirements.

We are subject to fraud and abuse and similar laws and regulations, and a failure to comply with such regulations or prevail in any litigation related to noncompliance could harm our business, financial condition and results of operations.

In the U.S., we are subject to various federal and state healthcare fraud and abuse laws, including anti-kickback laws, false claims laws and other laws intended, among other things, to reduce fraud and abuse in federal and state healthcare programs. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug, or other good or service for which payment in whole or in part may be made under a federal healthcare program, such as Medicare or Medicaid. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting or causing to be presented for payment to the government, including the federal healthcare programs, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services to obtain money or property of any healthcare benefit program. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including penalties, fines or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers or the Pharmaceutical Research and Manufacturers of America s Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable

state law requirement we could be subject to penalties.

Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we are found in violation of one of these laws, we could be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from governmental funded federal or state healthcare programs and the curtailment or restructuring of our operations. If this occurs, our business, financial condition and results of operations may be materially adversely affected.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and any of our drug candidates that are ultimately approved for commercialization could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from any of our drug candidates that are ultimately approved for commercialization. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business, financial condition and results of operations will be adversely affected. Additionally, if we are unable to generate revenues from product sales, our potential for achieving profitability will be diminished and our need to raise capital to fund our operations will increase.

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If we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our drug candidates.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We are highly dependent upon our senior management, particularly Brian Lian, our President and Chief Executive Officer, and Michael Dinerman, our Chief Operating Officer. The loss of any of our key personnel could delay or prevent the development of our drug candidates. These personnel are at-will employees and may terminate their employment with us at any time; however, our current executive officers have agreed to provide us with at least 60 days advance notice of resignation pursuant to their employment agreements with us. The replacement of Dr. Lian or Dr. Dinerman likely would involve significant time and costs, and the loss of services of either individual may significantly delay or prevent the achievement of our business objectives. We do not maintain key person insurance on any of our employees.

From time to time, our management seeks the advice and guidance of certain scientific advisors and consultants regarding clinical and regulatory development programs and other customary matters. These scientific advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Competition for qualified personnel is intense, especially in the greater San Diego, California area where we have a substantial presence and need for highly skilled personnel. We may not be successful in attracting qualified personnel to fulfill our current or future needs. Competitors and others have in the past attempted, and are likely in the future to attempt, to recruit our employees. While our employees are required to sign standard agreements concerning confidentiality and ownership of inventions, we generally do not have employment contracts or non-competition agreements with any of our personnel. The loss of the services of any of our key personnel, the inability to attract or retain highly qualified personnel in the future or delays in hiring such personnel, particularly senior management and other technical personnel, could materially and adversely affect our business, financial condition and results of operations.

We will need to increase the size of our organization and may not successfully manage our growth.

We currently have only six full-time employees, one part-time employee and a small number of consultants, and our management systems currently in place are not likely to be adequate to support our future growth plans. Our ability to grow and to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance our operational, financial and management systems in conjunction with our potential future growth, it could have a material adverse effect on our business, financial condition and results of operations.

Our management s relative lack of public company experience could put us at greater risk of incurring fines or regulatory actions for failure to comply with federal securities laws and could put us at a competitive disadvantage, and could require our management to devote additional time and resources to ensure compliance with applicable corporate governance requirements.

Some of our executive officers have limited experience in managing and operating a public company, which could have an adverse effect on their ability to quickly respond to problems or adequately address issues and matters

applicable to public companies. Any failure to comply with federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, financial condition and results of operations. Further, since some of our executive officers have minimal public company experience, we may have to dedicate additional time and resources to comply with legally mandated corporate governance policies relative to our competitors whose management teams have more public company experience.

We are exposed to product liability, non-clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. In addition, the use in our clinical trials of pharmaceutical products and the subsequent sale of these products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

Because we do not currently have any clinical trials ongoing, we do not currently carry product liability insurance. We anticipate obtaining such insurance upon initiation of our clinical development activities; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Our research and development activities involve the use of hazardous materials, which subject us to regulation, related costs and delays and potential liabilities.

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds, and we will need to develop additional safety procedures for the handling and disposing of hazardous materials. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws

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and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our drug development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of drug development or clinical trial data 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 our development programs and the development of our drug candidates could be delayed.

Our employees and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Employee and consultant misconduct also could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us.

Business disruptions such as natural disasters could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our corporate headquarters are located in greater San Diego, California, a region known for seismic activity. Our suppliers may also experience a disruption in their business as a result of natural disasters. A significant natural disaster, such as an earthquake, flood or fire, occurring at our headquarters or facilities or where our suppliers are located, could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts or acts of war targeted at the U.S., and specifically the greater San Diego, California region, could cause damage or disruption to us, our employees, facilities, partners and suppliers, which could have a material

adverse effect on our business, financial condition and results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, drug candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our business, financial condition and results of operations. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention in order to develop acquired products, drug candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for any of these transactions;
- higher-than-expected transaction and integration costs;
- write-downs of assets or goodwill or impairment charges;

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increased amortization expenses;

difficulty and cost in combining the operations and personnel of any acquired businesses or product lines with our operations and personnel;

impairment of relationships with key suppliers or customers of any acquired businesses or product lines due to changes in management and ownership; and

inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could have a material adverse effect on our business, financial condition and results of operations.

Our employment agreements with each of 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 our company, which could harm our financial condition or results.

All of our executive officers are parties to employment agreements that contain change in control and severance provisions in the event of a termination of employment in connection with a change in control of our company providing for cash payments for severance and other benefits and acceleration of vesting of stock options and shares of restricted stock. The accelerated vesting of options and shares of restricted stock could result in dilution to our existing stockholders and lower 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.

Risks Relating to Our Intellectual Property

We may not be successful in obtaining or maintaining necessary rights to our drug candidates through acquisitions and in-licenses.

We currently have intellectual property rights to develop our drug candidates through licenses from Ligand. As of March 31, 2015, we did not own any patents or have any patent applications pending. Because many of our programs require the use of proprietary rights held by Ligand, the growth of our business will likely depend in part on our ability to maintain and exploit these proprietary rights. In addition, we may need to acquire or in-license additional intellectual property in the future. We may be unable to acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our drug candidates. We face competition with regard to acquiring and in-licensing third-party intellectual property rights, including from a number of more established companies. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license intellectual property rights to us. We also may be unable to acquire or in-license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We may enter into collaboration agreements with U.S. and foreign academic institutions to accelerate development of our current or future preclinical drug candidates. Typically, these agreements include an option for the company to

negotiate a license to the institution s intellectual property rights resulting from the collaboration. Even with such an option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to license rights from a collaborating institution, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our desired program.

If we are unable to successfully obtain required third-party intellectual property rights or maintain our existing intellectual property rights, we may need to abandon development of the related program and our business, financial condition and results of operations could be materially and adversely affected.

If we fail to comply with our obligations in the agreements under which we in-license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

The Master License Agreement is important to our business and we expect to enter into additional license agreements in the future. The Master License Agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or if we file for bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses could materially and adversely affect our business, financial condition and results of operations.

Pursuant to the terms of the Master License Agreement, Ligand may terminate the Master License Agreement under certain circumstances, including, but not limited to: (1) in the event of our insolvency or bankruptcy, (2) if we do not pay an undisputed amount owing under the Master License Agreement when due and fail to cure such default within a specified period of time, or (3) if we default on certain of our material obligations and fail to cure the default within a specified period of time. If the Master License Agreement is terminated in its entirety or with respect to a specific licensed program for any reason, among other consequences, all licenses granted to us under the Master License

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Agreement (or with respect to the specific licensed program) will terminate and we may be requested to assign and transfer to Ligand certain regulatory documentation and regulatory approvals related to the licensed programs (or those related to the specific licensed program), and we may be required to wind down any ongoing clinical trials with respect to the licensed programs (or those related to the specific licensed program). Additionally, Ligand may require us to assign to Ligand the trademarks owned by us relating to the licensed programs (or those related to the specific licensed program), and we would be obligated to grant to Ligand a license under any patent rights and know-how controlled by us to the extent necessary to make, have made, import, use, offer to sell and sell the licensed programs (or those related to the specific licensed program) anywhere in the world at a royalty rate in the low single digits.

In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we in-license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates. If we fail to comply with any such obligations to our licensor, such licensor may terminate their licenses to us, in which case we would not be able to market products covered by these licenses. The loss of our license with Ligand, and potentially other licenses that we enter into in the future, would have a material adverse effect on our business.

We may be required to pay milestones and royalties to Ligand in connection with our use of the licensed technology under the Master License Agreement, which could adversely affect the overall profitability for us of any products that we may seek to commercialize.

Under the terms of the Master License Agreement, we may be obligated to pay Ligand up to an aggregate of approximately $1,54 billion in development, regulatory and sales milestones. We will also be required to pay Ligand single-digit royalties on future worldwide net product sales. These royalty payments could adversely affect the overall profitability for us of any products that we may seek to commercialize.

We may not be able to protect our proprietary or licensed technology in the marketplace.

We depend on our ability to protect our proprietary or licensed technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability, Ligand s and any future licensor s or licensee s ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary or licensed technology and products. We believe we will be able to obtain, through prosecution of patent applications covering technology licensed from others, adequate patent protection for our proprietary drug technology, including those related to our in-licensed intellectual property. If we are compelled to spend significant time and money protecting or enforcing our licensed patents and future patents we may own, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business, financial condition and results of operations may be materially and adversely affected. If we are unable to effectively protect the intellectual property that we own or in-license, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our business, financial condition and results of operations. The patents of others from whom we may license technology, and any future patents we may own, may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our products.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the U.S. and many jurisdictions outside of the U.S. is not consistent. For example, in many jurisdictions, the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our licensed or owned intellectual property or create uncertainty. In addition, publication of information related to our current drug candidates and potential products may prevent

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us from obtaining or enforcing patents relating to these drug candidates and potential products, including without limitation composition-of-matter patents, which are generally believed to offer the strongest patent protection.

Our intellectual property includes licenses covering issued patents and pending patent applications for composition of matter and method of use. For VK5211, we in-license six patents in the U.S. and several other patents in certain foreign jurisdictions. For each of VK2809 and VK0214, we in-license a patent in the U.S. and, for VK2809, additional patents in certain foreign jurisdictions. For VK0612, we in-license two patents in the U.S. and several other patents in certain foreign jurisdictions. With respect to our other current drug candidates, we have a license covering several issued patents and pending patent applications both in the U.S. and in certain foreign jurisdictions.

Patents that we currently license and patents that we may own or license in the future do not necessarily ensure the protection of our licensed or owned intellectual property for a number of reasons, including without limitation the following:

- the patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our drug candidates;
- there can be no assurance that the term of a patent can be extended under the provisions of patent term extension afforded by U.S. law or similar provisions in foreign countries, where available;
- the issued patents and patents that we may obtain or license in the future may not prevent generic entry into the U.S. market for our drug candidates;
- we do not at this time license or own a granted European patent or national phase patents in any European jurisdictions that would prevent generic entry into the European market for our primary drug candidate, VK5211;
- we, or third parties from who we in-license or may license patents, may be required to disclaim part of the term of one or more patents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- there may be other patents issued to others that will affect our freedom to operate;

- if the patents are challenged, a court could determine that they are invalid or unenforceable;
- there might be a significant change in the law that governs patentability, validity and infringement of our licensed patents or any future patents we may own that adversely affects the scope of our patent rights;
- a court could determine that a competitor s technology or product does not infringe our licensed patents or any future patents we may own; and
- the patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

If we encounter delays in our development or clinical trials, the period of time during which we could market our potential products under patent protection would be reduced.

Our competitors may be able to circumvent our licensed patents or future patents we may own by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our licensed patents or any future patents we may own are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our licensed patents or any future patents we may own, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our licensed patents or any future patents we may own invalid or unenforceable. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we own or in-license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In this regard, third parties may challenge our licensed patents or any future patents we may own in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and potential products. In addition, given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized.

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We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and prevent us from commercializing or increase the costs of commercializing our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or potential future drug candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our drug candidates or potential products infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our drug candidates or potential products infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our drug candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our drug candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless we acquire or obtain a license under the applicable patents or until the patents expire.

We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition and results of operations. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Any claims or lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely affect our business, financial condition and results of operations.

We may be required to initiate litigation to enforce or defend our licensed and owned intellectual property. These lawsuits can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the biopharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. 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 litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our licensed patents and patent applications, and patents and patent applications that we may own or license in the future, could face other challenges, such as interference proceedings, opposition proceedings, re-examination proceedings and other forms of post-grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our licensed patents and patent applications and patents and patent applications that we may own or license in the future subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel s time and attention.

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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 material adverse effect on the market price of our common stock.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. For example, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Specifically, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law and included a number of significant changes to U.S. patent law. These included changes in the way patent applications will be prosecuted, including a transition to a first-to-file system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention, and may also affect patent litigation. Under a first-to-file system, a third party that files a patent application with the U.S. Patent and Trademark Office, or the USPTO, before us could be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures that may make it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on our business, the cost of prosecuting our licensed and future patent applications, our ability to obtain patents based on our licensed and future patent applications and our ability to enforce or defend our licensed or future issued patents. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our licensed and future patent applications and the enforcement or defense of our licensed and future patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future.

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

Filing, prosecuting and defending patents on drug candidates throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future 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 licensed patents and future patents we may own, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our licensed and owned intellectual property both in the U.S. and abroad. For example, China, where we currently have seven licensed patents and three licensed patent applications, currently affords less protection to a company s intellectual property than some other jurisdictions. As such, the lack of strong patent and other intellectual property protection in China may significantly increase our vulnerability as regards unauthorized disclosure or use of our intellectual property and undermine our competitive position. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. In those countries, we currently have an aggregate of 18 licensed patents and 17 licensed patent applications and may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of

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unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biopharmaceutical companies. Although we have no knowledge of any such claims against us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. To date, none of our employees have been subject to such claims.

We may be subject to claims challenging the inventorship of our licensed patents, any future patents we may own and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our licensed patents or our licensed or owned intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our licensed patents or other licensed or owned intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected.

Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our licensed U.S. patents or future U.S. patents that we may license or own may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one-half the time between the effective date of an investigational new drug application, or IND (falling after issuance of the patent), and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or

restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected.

Risks Relating to Ownership of Our Common Stock

The market price of our common stock may be highly volatile.

The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in filing an NDA for any of our drug candidates and any adverse development or perceived adverse development with respect to the FDA s review of that NDA;
- adverse results or delays in clinical trials, if any;
- significant lawsuits, including patent or stockholder litigation;
- inability to obtain additional funding;
- failure to successfully develop and commercialize our drug candidates;
- changes in laws or regulations applicable to our drug candidates;

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inability to obtain adequate product supply for our drug candidates, or the inability to do so at acceptable prices;

unanticipated serious safety concerns related to any of our drug candidates;

adverse regulatory decisions;

introduction of new products or technologies by our competitors;

failure to meet or exceed drug development or financial projections we provide to the public;

failure to meet or exceed the estimates and projections of the investment community;

the perception of the biopharmaceutical industry by the public, legislatures, regulators and the investment community;

announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our licensed and owned technologies;

additions or departures of key scientific or management personnel;

changes in the market valuations of similar companies;

general economic and market conditions and overall fluctuations in the U.S. equity market;

sales of our common stock by us or our stockholders in the future; and

trading volume of our common stock.

In addition, the stock market, in general, and small biopharmaceutical companies, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, a decline in the financial markets and related factors beyond

our control may cause our stock price to decline rapidly and unexpectedly.

An active trading market for our common stock may not be sustained, and you may not be able to resell your common stock at a desired market price.

Our shares of common stock began trading on the Nasdaq Capital Market on April 29, 2015. If an active market for our common stock does not develop, you may not be able to sell your shares quickly or at an acceptable price. If no active trading market for our common stock is sustained, you may be unable to sell your shares when you wish to sell them or at a price that you consider attractive or satisfactory. The lack of an active market may also adversely affect our ability to raise capital by selling securities in the future, or impair our ability to acquire or in-license other drug candidates, businesses or technologies using our shares as consideration.

Our management owns a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of June 1, 2015, our executive officers, directors, 5% or greater stockholders and their affiliates and family members beneficially own 75.4% of our common stock. Therefore, our executive officers, directors, 5% or greater stockholders and their affiliates and family members have the ability to influence us through this ownership position.

This significant concentration of stock ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, these stockholders, if they acted together, could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. These stockholders may be able to determine all matters requiring stockholder approval. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders. This may also prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Ligand is our largest stockholder, which may limit the ability of our stockholders to influence corporate matters and may give rise to conflicts of interest.

As of June 1, 2015, Ligand and its affiliates beneficially own approximately 48.9% of our outstanding common stock. In addition to the above ownership, Ligand may elect to convert the amounts outstanding under that certain Secured Convertible Promissory Note held by Ligand, or the Ligand Note, upon the earlier of (1) the consummation of a bona fide capital financing transaction or series of financing transactions with

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one or more financial non-strategic investors with aggregate net proceeds to us of at least $20,000,000 and pursuant to which we issue shares of our equity securities, (2) the consummation of a firmly underwritten public offering pursuant to the Securities Act of 1933, as amended, or the Securities Act, on Form S-1 or Form S-3, or any successor forms, and (3) May 4, 2016 (the one year anniversary of the closing of our initial public offering). Upon the occurrence of such an event, Ligand will have the option to convert the amounts outstanding under the Ligand Note into shares of our common stock and receive an additional 647,465 shares of our common stock upon conversion of the Ligand Note based on $2,589,861 of principal and interest outstanding under the Ligand Note as of March 31, 2015. Accordingly, Ligand may be able to exert significant influence over us and any action requiring the approval of the holders of our common stock, including the election of directors and the approval of mergers or other business combination transactions. This concentration of voting power may make it less likely that any other holder of our common stock or our board of directors will be able to affect the way we are managed and could delay or prevent an acquisition of us on terms that other stockholders may desire.

Furthermore, the interests of Ligand may not be aligned with our other stockholders and this could lead to actions that may not be in the best interests of our other stockholders. For example, Ligand may have different tax positions or strategic plans for us, which could influence its decisions regarding whether and when we should dispose of assets or incur new or refinance existing indebtedness. In addition, Ligand s significant ownership in us may discourage someone from making a significant equity investment in us, or could discourage transactions involving a change in control, including transactions in which our stockholders might otherwise receive a premium for their shares over the then-current market price.

Pursuant to the management rights letter between us and Ligand, dated May 21, 2014, Ligand has the right to nominate one individual for election to our board of directors. Matthew W. Foehr, Ligand s President and Chief Operating Officer, is the current member of our board of directors nominated by Ligand. As a result of our relationship with Ligand, there may be transactions between us and Ligand that could present an actual or perceived conflict of interest. These conflicts of interest may lead Mr. Foehr to recuse himself from actions of our board of directors with respect to any transactions involving Ligand or its affiliates.

In addition, if Ligand obtains a majority of our common stock, Ligand would be able to control a number of matters submitted to our stockholders for approval, as well as our management and affairs. For example, Ligand would be able to control the election of directors, and may be able to control amendments to our organizational documents and approvals of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization. In addition, if Ligand obtains a majority of our common stock, we would be deemed a controlled company within the meaning of the rules and listing standards of The Nasdaq Stock Market LLC. Under the rules and listing standards of The Nasdaq Stock Market LLC, a company of which more than 50% of the voting power is held by another person or group of persons acting together is a controlled company and may elect not to comply with certain rules and listing standards of The Nasdaq Stock Market LLC regarding corporate governance, including: (1) the requirement that a majority of our board of directors consist of independent directors, (2) the requirement that the compensation of our officers be determined or recommended to our board of directors by a compensation committee that is composed entirely of independent directors, and (3) the requirement that director nominees be selected or recommended to our board of directors by a majority of independent directors or a nominating committee that is composed entirely of independent directors.

We are an emerging growth company within the meaning of the Securities Act, and if we decide to take advantage of certain exemptions from various reporting requirements applicable to emerging growth companies, our common stock could be less attractive to investors.

For as long as we remain an emerging growth company , as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we will have the option to take advantage of certain exemptions from various reporting and other requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, 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 may take advantage of these and other exemptions until we are no longer an emerging growth company .

The JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. However, we have chosen to opt out of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Our decision to opt out of the extended transition period is irrevocable.

We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year during which we have total annual gross revenues of $1.0 billion or more, (2) December 31, 2020 (the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering), (3) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt, and (4) the date on which we are deemed to be a large accelerated filer under the Securities Exchange Act of 1934, as amended, or the Exchange Act (i.e., the first day of the fiscal year after we have (a) more than $700,000,000 in outstanding common equity held by our non-affiliates, measured each year on the last day of our second fiscal quarter, and (b) been public for at least 12 months).

Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these

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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 be more volatile.

Our internal control over financial reporting does not currently meet the standards required by Section 404 of the Sarbanes-Oxley Act, and we have previously identified a material weakness, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, could have a material adverse effect on our business and share price.

As a privately held company, we were not required to evaluate our internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Commencing with our Annual Report on Form 10-K for the fiscal year ending December 31, 2016, our management will be required to report on the effectiveness of our internal control over financial reporting. Additionally, under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an emerging growth company. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies or material weaknesses that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm. Failure to achieve and maintain an effective internal control environment could have a material adverse effect on our business, financial condition and results of operations and could limit our ability to report our financial results accurately and in a timely manner.

In the course of auditing our financial statements as of and for the year ended December 31, 2013, our independent registered public accounting firm identified a material weakness in our internal control over financial reporting relating to our failure to perform periodic reconciliations on various accounts. The material weakness resulted in adjusting entries to our financial statements and delays in producing such financial information to our independent registered public accounting firm. We remediated this material weakness in the year ended December 31, 2014 primarily by adding personnel to our accounting staff and implementing reconciliation policies and procedures, including effective review and oversight, to ensure the timely delivery and accuracy of financial information and minimize the risk of misstatement or misappropriation. These planned actions are subject to ongoing management review and the oversight of the audit committee of our board of directors. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to avoid potential future material weaknesses.

We will incur significant increased costs as a result of operating as a public company, our management has limited experience managing a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company and particularly after we cease to be an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, or the Dodd-Frank Act, as well as rules subsequently implemented by the SEC and The Nasdaq Stock Market LLC have imposed various requirements on public companies. There are significant corporate governance and executive compensation related provisions in the

Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such insurance coverage.

As a publicly traded company, we have incurred and will incur legal, accounting and other expenses associated with the SEC reporting requirements applicable to a company whose securities are registered under the Exchange Act, as well as corporate governance requirements, including those under the Sarbanes-Oxley Act, the Dodd-Frank Act and other rules implemented by the SEC and The Nasdaq Stock Market LLC. In addition, we expect that we will need to hire additional personnel in our finance department to help us comply with the various requirements applicable to public companies. The expenses incurred by public companies generally to meet SEC reporting, finance and accounting and corporate governance requirements have been increasing in recent years as a result of changes in rules and regulations and the adoption of new rules and regulations applicable to public companies.

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. 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. In addition, if our operating results fail to meet the forecast of analysts, our stock price would

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likely decline. 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.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

Our executive officers, directors, 5% or greater stockholders and their affiliates and family members are subject to lock-up agreements with the underwriters of our initial public offering that restrict these stockholders ability to transfer shares of our common stock until October 25, 2015, or, in the case of Ligand, until January 23, 2016, except with respect to the Ligand Note and the shares issuable to Ligand under the Ligand Note. Subject to certain limitations, including sales volume limitations with respect to shares held by our affiliates, substantially all of the shares held by these stockholders will be eligible for sale in the public market upon expiration of the applicable lock-up period. In addition, shares issued or issuable upon exercise of options vested as of the expiration of the applicable lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders, or the perception that these sales may occur, could have a material adverse effect on the trading price of our common stock.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business, financial condition and results of operations.

Our ability to use our net operating loss carryforwards may be subject to certain limitations.

At December 31, 2014, we had net operating loss carryforwards of approximately $1,402,000 for both federal and state tax purposes, which begin to expire in 2032. Our ability to utilize our federal net operating loss carryforwards may be limited under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. Specifically, this limitation may arise in the event of an ownership change, which is defined by Section 382 of the Code as a cumulative change in ownership of our company of more than 50% within a three-year period. We do not believe that we have experienced an ownership change at any time in the past. However, if a taxing authority disagrees with us, or if we undergo one or more ownership changes in connection with future transactions in our stock, our ability to utilize net operating loss carryforwards to offset federal taxable income, if any, could be limited by Section 382, which could potentially result in increased future tax liability to us.

We may never pay dividends on our common stock so any returns would be limited to the appreciation of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult or expensive for a third party to acquire us or change our board of directors or current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

limiting the removal of directors by the stockholders;

creating a classified board of directors;

providing that no stockholder is permitted to cumulate votes at any election of directors;

allowing the authorized number of our directors to be changed only by resolution of our board of directors;

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prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

requiring the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our charter documents;

eliminating the ability of stockholders to call a special meeting of stockholders; and

establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings.

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, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved in advance by our board of directors or ratified by our board of directors and certain of our stockholders. This provision could have the effect of delaying or preventing a change in control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or our directors, officers or employees arising pursuant to any provision of our amended and restated bylaws, our amended and restated certificate of incorporation or the DGCL, (4) any action asserting a claim against us or our directors, officers or employees that is governed by the internal affairs doctrine, or (5) any action to interpret, apply, enforce or determine the validity of our amended and restated bylaws or our amended and restated certificate of incorporation. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our amended and restated bylaws. This choice-of-forum provision may limit our stockholders ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. Alternatively, if a court were to find this provision of our amended and restated bylaws inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

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

Use of Proceeds

On May 4, 2015, we sold 3,000,000 shares of our common stock in our initial public offering at a public offering price of $8.00 per share and on May 28, 2015, we sold 450,000 shares of our common stock at a public offering price of $8.00 per share pursuant to the full exercise of the underwriters option to purchase additional shares for aggregate gross proceeds of $27,600,000, before deducting underwriting discounts, commissions and other offering expenses. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-197182), which was declared effective by the SEC on April 28, 2015, and a registration statement on Form S-1MEF (File No. 333-203702) filed pursuant to Rule 462(b) of the Securities Act. The offering commenced as of April 29, 2015 and did not terminate before all of the securities registered in the registration statements were sold. Laidlaw & Company (UK) Ltd. acted as the sole book-running manager for the offering. Feltl and Company, Inc. served as co-manager for the offering. After deducting underwriting discounts, commissions and estimated offering costs paid by us of $5,227,500, the net proceeds from the offering were $22,372,500. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

The net proceeds from our initial public offering have been deposited into money market funds and we intend to invest these proceeds in the future in some combination of government agency and/or corporate securities, with the balance of the net proceeds to be invested in money market funds in accordance with our investment policy. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) of the Securities Act.

Item 6. Exhibits

The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed as part of this Quarterly Report on Form 10-Q and such Exhibit Index is incorporated herein by reference.

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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.

Viking Therapeutics, Inc.

Date: June 11, 2015

By: /s/ Brian Lian, Ph.D.
Brian Lian, Ph.D.
President, Chief Executive Officer and Director

(Principal Executive Officer)

Date: June 11, 2015

By: /s/ Michael Morneau
Michael Morneau
Chief Financial Officer

(Principal Accounting and Financial Officer)

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EXHIBIT INDEX

Exhibit No.	Description of Document
3.1	Amended and Restated Certificate of Incorporation (previously filed on July 1, 2014 as Exhibit 3.3 to the Registrant s Registration Statement on Form S-1 (File No. 333-197182) and incorporated herein by reference).
3.2	Amended and Restated Bylaws (previously filed on July 1, 2014 as Exhibit 3.4 to the Registrant s Registration Statement on Form S-1 (File No. 333-197182) and incorporated herein by reference).
4.1	Form of Common Stock Certificate (previously filed on July 1, 2014 as Exhibit 4.1 to the Registrant s Registration Statement on Form S-1 (File No. 333-197182) and incorporated herein by reference).
10.1*#	Amended and Restated Stock Repurchase Agreement, dated April 28, 2015, by and among Viking Therapeutics, Inc., Brian Lian, Ph.D., Michael Dinerman, M.D., Isabelle Dinerman and Rochelle Hanley, M.D.
10.2*#	Amendment No. 1 to Founder Common Stock Purchase Agreement, dated May 4, 2015, by and between Viking Therapeutics, Inc. and Brian Lian, Ph.D.
10.3*#	Amendment No. 1 to Founder Common Stock Purchase Agreement, dated May 4, 2015, by and between Viking Therapeutics, Inc. and Michael Dinerman, M.D.
10.4*#	Amendment No. 1 to Common Stock Purchase Agreement, dated May 4, 2015, by and between Viking Therapeutics, Inc. and Rochelle Hanley, M.D.
10.5*#	Amendment No. 1 to Common Stock Purchase Agreement, dated May 4, 2015, by and between Viking Therapeutics, Inc. and Brian Lian, Ph.D.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
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.

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014, (ii) Condensed

Consolidated Statements of Comprehensive Income for the three months ended March 31, 2015 and March 31, 2014, (iii) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and March 31, 2014, and (iv) Notes to Condensed Consolidated Financial Statements.

* Filed herewith.
# Indicates compensatory plan or arrangement.