Evoke Pharma Inc
Form 10-Q
November 13, 2013

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 September 30, 2013

OR

¨ **TRANSITION REPORT UNDER SECTION 13 OF 15(d) OR THE EXCHANGE ACT OF 1934**

Commission File Number 001-36075

EVOKE PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-8447886**

(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)
12555 High Bluff Drive, Suite 385, San Diego, CA	92130
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: (760) 487-1255

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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of October 31, 2013 there were 6,096,752 shares of common stock of the issuer outstanding.

EVOKE PHARMA, INC.

FORM 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Evoke Pharma, Inc.

(A Development Stage Company)

Condensed Balance Sheets

	September 30, 2013 (unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 23,738,053	$ 116,013
Total current assets	23,738,053	116,013
Total assets	$ 23,738,053	$ 116,013
Liabilities, convertible preferred stock and stockholders equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,176,226	$ 96,798
Accrued compensation	390,981	417,611
Warrant liability		56,000
Current portion of long-term debt, net of debt discount	1,069,802	
Total current liabilities	2,637,009	570,409
Long-term debt, net of current portion	1,878,436	979,792
Total liabilities	4,515,445	1,550,201
Commitments and contingencies		
Series A convertible preferred stock, $0.0001 par value; authorized shares 0 at September 30, 2013 and 12,245,068 at December 31, 2012; issued and outstanding shares 0 at September 30, 2013 and 12,195,068 at December 31, 2012		18,225,166
Stockholders equity (deficit):		
Preferred stock, $0.0001 par value; authorized shares 5,000,000 at September 30, 2013 and 0 at December 31, 2012; issued and outstanding shares 0 at September 30, 2013 and December 31, 2012		
Common stock, $0.0001 par value; authorized shares 50,000,000 at September 30, 2013 and 20,000,000 at December 31, 2012; issued and outstanding shares 5,781,752 at September 30, 2013 and 1,242,750 at December 31, 2012	578	124
Additional paid-in capital	40,296,800	195,525
Deficit accumulated during the development stage	(21,074,770)	(19,855,003)

Total stockholders equity (deficit)	19,222,608		(19,659,354)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	$ 23,738,053	$	116,013

See accompanying notes to unaudited condensed financial statements.

Evoke Pharma, Inc.

(A Development Stage Company)

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period From January 29, 2007 (inception) to September 30,
	2013	2012	2013	2012	2013
Operating expenses:					
Research and development	$ 78,731	$ 337,003	$ 320,558	$ 847,298	$ 16,312,087
General and administrative	406,862	140,746	700,489	493,210	4,005,022
Purchase of in-process research and development					650,000
Total operating expenses	485,593	477,749	1,021,047	1,340,508	20,967,109
Loss from operations	(485,593)	(477,749)	(1,021,047)	(1,340,508)	(20,967,109)
Other income (expense)					
Interest income	629	466	2,850	1,401	216,702
Interest expense	(39,940)	(10,521)	(119,570)	(10,521)	(325,512)
Change in fair value of preferred stock purchase right					(188,587)
Change in fair value of warrant liability	39,000	1,550	(82,000)	4,550	(54,264)
Grant income					244,000
Total other income (expense)	(311)	(8,505)	(198,720)	(4,570)	(107,661)
Net loss and comprehensive loss	$ (485,904)	$ (486,254)	$ (1,219,767)	$ (1,345,078)	$ (21,074,770)
Net loss per common share, basic and diluted	$ (0.41)	$ (0.43)	$ (1.06)	$ (1.20)	
Weighted-average shares used to compute basic and diluted net loss per share	1,190,212	1,125,875	1,153,751	1,122,125	

See accompanying notes to unaudited condensed financial statements.

Evoke Pharma, Inc.

(A Development Stage Company)

Condensed Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30, 2013	2012	Period From January 29, 2007 (inception) to September 30, 2013
Operating activities			
Net loss	$ (1,219,767)	$ (1,345,078)	$ (21,074,770)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	13,881	9,378	103,592
Non-cash interest	17,446	2,021	123,512
Change in fair value of purchase right liability			188,587
Change in fair value of warrant liability	82,000	(4,550)	54,264
Changes in operating assets and liabilities:			
Prepaid expenses and other assets		39,459	
Accounts payable and accrued expenses	(44,562)	201,666	469,847
Net cash used in operating activities	(1,151,002)	(1,097,104)	(20,134,968)
Financing activities			
Proceeds from convertible promissory note			250,000
Proceeds from bank line of credit and loan advances	2,000,000	1,000,000	5,500,000
Payment on bank line of credit			(2,500,000)
Proceeds from issuance of common stock	25,200,000		25,204,580
Cash paid in connection with initial public offering	(2,426,958)		(2,426,958)
Proceeds from issuance of preferred stock and purchase rights, net			17,744,041
Proceeds from exercise of stock options			101,358
Net cash provided by financing activities	24,773,042	1,000,000	43,873,021
Net change in cash and cash equivalents	23,622,040	(97,104)	23,738,053
Cash and cash equivalents at beginning of the period	116,013	865,876	
Cash and cash equivalents at end of the period	$ 23,738,053	$ 768,772	$ 23,738,053
Supplemental disclosures of cash flow information			
Interest paid	$ 94,750	$ 4,750	$ 194,626
Supplemental disclosures of noncash financing information			

Conversion of convertible promissory note and accrued interest to Series A Convertible Preferred Stock	$	$	$ 292,538
Issuance of Series A Convertible Preferred Stock warrants	$ 49,000	$ 24,250	$ 108,486

See accompanying notes to unaudited condensed financial statements.

Evoke Pharma, Inc.

(A Development Stage Company)

Notes to Condensed Financial Statements

(Unaudited)

1. Organization and Basis of Presentation

Evoke Pharma, Inc. (the Company) was incorporated in the state of Delaware on January 29, 2007 (inception). The Company is a specialty pharmaceutical company focused primarily on the development of drugs to treat gastroenterological disorders and disease.

As of September 30, 2013, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure, and has not realized revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

Reverse Stock Split

On August 30, 2013, the Company filed an amendment to its amended and restated certificate of incorporation, effecting a one-for-five reverse stock split of the Company s issued and outstanding shares of common stock. All issued and outstanding common stock and per share amounts contained in the Company s financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

Unaudited Interim Financial Information

The accompanying interim condensed financial statements are unaudited. These unaudited interim financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) and following the requirements of the U.S. Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. In management s opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company s financial position and its results of operations and comprehensive loss and its cash flows for periods presented. These statements do not include all disclosures required by GAAP and should be read in conjunction with the Company s financial statements and accompanying notes for the fiscal year ended December 31, 2012, which is contained in the Company s final prospectus filed by the Company with the SEC on September 25, 2013 relating to the Company s Registration Statement on Form S-1/A (File No. 333-188838) for the Company s initial public offering (IPO). The results for interim periods are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Initial Public Offering and Related Transactions

On September 30, 2013, the Company completed its IPO whereby it sold 2,100,000 shares of common stock at a price of $12.00 per share. Net proceeds from the IPO were determined as follows:

Gross proceeds (excluding over-allotment)	$ 25,200,000
Underwriting discounts and commissions and non-accountable expense allowance	(2,080,275)
Total offering costs (excluding value of warrants granted to underwriter of $470,000)	(1,444,043)
Net proceeds	$ 21,675,682

Additionally, upon the closing of the IPO, certain transactions occurred based on a successful completion of the IPO:

the conversion of all outstanding shares of convertible preferred stock into 2,439,002 shares of the Company s common stock;

retention bonuses in the amount of $355,000 became payable to the Company s executive officers. Such amount will be recorded as expense on a straight-line basis from May 22, 2013 (the date of the retention agreements entered into with the executive officers) through December 24, 2013, the date at which the final payment is due based on continued employment. Since the terms of the payment required the occurrence of either a change in control of the Company, or an equity financing, neither of which are considered probable to occur until they happen, a catch-up expense of $202,857 was recorded at the time of the Company s IPO. Should the executive officers voluntarily terminate their employment or are terminated by the Company for cause, the executive would forfeit any portion of the retention payment that has not been paid to them;

the issuance of warrants to purchase 84,000 shares of the Company s common stock to the representative of the underwriters of the Company s IPO and certain of its affiliates. The warrants will become exercisable at a price of $21.00 per share beginning on September 24, 2014 and will expire on September 24, 2018. The $470,000 initial fair value of the warrants was determined using the Black-Scholes option pricing model and recorded as a cost of the Company s IPO and charged to additional paid-in capital;

The fair value of the issued warrants was estimated using the Black-Scholes option pricing model with the following assumptions:

Assumed risk-free interest rate	1.44%
Assumed volatility	71%
Expected warrant life	5 years
Expected dividend yield	0.0%

the conversion of warrants to purchase 110,000 shares of convertible preferred stock into warrants to purchase 22,000 shares of the Company s common stock and the resultant reclassification of the $187,000 warrant liability to additional paid-in capital; and

the filing of an amended and restated certificate of incorporation to authorize 50,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock.

In addition to the above, the following benefit plans became effective in connection with the Company s IPO:

2013 Equity Incentive Award Plan

The 2013 Equity Incentive Award Plan (2013 Plan) became effective on the day prior to the public trading date of our common stock. Under the 2013 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. A total of 510,000 shares of common stock were initially reserved for issuance under the 2013 Plan. In addition, the number of shares of common stock available for issuance under the

2013 Plan will be annually increased on the first day of each fiscal year during the term of the 2013 Plan, beginning with the 2014 fiscal year, by an amount equal to the least of: (i) 300,000 shares; (ii) four percent of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) such other amount as the Company s board of directors may determine.

Employee Stock Purchase Plan

The Employee Stock Purchase Plan (ESPP) became effective on the day prior to the public trading date of our common stock. The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation. A total of 30,000 shares of common stock were initially reserved for issuance under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP will be annually increased on the first day of each fiscal year during the term of the ESPP, beginning with the 2014 fiscal year, by an amount equal to the least of: (i) 30,000 shares; (ii) one percent of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) such other amount as the Company s board of directors may determine.

On October 3, 2013, the underwriters for the Company s IPO exercised their over-allotment option to purchase an additional 315,000 shares of the Company s common stock at $12.00 per share. The over-allotment exercise is expected to result in estimated net proceeds to the Company of $3,440,400, after deducting $264,600 of underwriting discounts and commissions and an estimated $75,000 of additional offering costs.

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board issued an accounting standard update to require reclassification adjustments from other comprehensive income to be presented either in the financial statements or in the notes to the financial statements. This accounting standard became effective for the Company beginning in the first quarter of 2013, and its adoption did not have any impact on the Company s financial statements.

2. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted-average number of common shares outstanding that are subject to repurchase. The Company has excluded 101,875, 116,875, 105,625 and 120,625 weighted-average shares subject to repurchase from the weighted-average number of common shares outstanding for the three months ended September 30, 2013 and 2012 and the nine months ended September 30, 2013 and 2012, respectively. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of convertible preferred stock, warrants for the purchase of convertible preferred stock, warrants for the purchase of common stock, and options outstanding under the Company s equity incentive plans. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company s net loss position.

The following table summarizes the weighted-average anti-dilutive securities excluded from the calculation of diluted net loss per share (in common stock equivalent shares):

	Three and Nine Months Ended September 30,	
	2013	**2012**
Convertible preferred stock outstanding		2,439,002
Warrants for convertible preferred stock		14,000
Warrants for common stock	106,000	
Common stock options	231,250	123,250
	337,250	2,576,252

3. Fair Value Measurements

The following tables present information about the Company s financial liabilities measured at fair value on a recurring basis, and indicate the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value. As a basis for categorizing inputs, the Company uses a three-tier fair value hierarchy, which prioritizes the inputs used to measure fair value from market based assumptions to entity specific assumptions:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company s Level 3 financial liabilities consist of warrant liabilities related to warrants to purchase preferred stock. All warrants are being measured at fair value utilizing the Black-Scholes option pricing model.

The fair value of the outstanding preferred stock warrants at December 31, 2012 was estimated using the Black-Scholes option pricing model with the following assumptions:

	December 31, 2012
Assumed risk-free interest rate	0.25 1.78%
Assumed volatility	80%
Expected warrant life	2.08 9.50 years
Expected dividend yield	0.0%

The warrant liability was adjusted to its fair value of $187,000 prior to the closing of the Company s IPO on September 30, 2013. As a result of the IPO, all of the Company s outstanding preferred stock warrants became exercisable for common stock, are no longer required to be recorded as liabilities, and were reclassified to additional paid-in capital as of September 30, 2013. As such, there are no remaining liabilities measured at fair value on a recurring basis as of September 30, 2013.

Liabilities measured at fair value on a recurring basis as of December 31, 2012 are as follows:

		Fair Value Measurements at Reporting Date Using		
	Balance as of December 31, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Preferred stock warrant liability	$ 56,000	$ 0	$ 0	$ 56,000
Total liabilities	$ 56,000	$ 0	$ 0	$ 56,000

The following table is a reconciliation of all the Company s liabilities measured using significant unobservable inputs (Level 3) for the year ended December 31, 2012 and the nine months ended September 30, 2013:

	Warrant Liability
Balance at December 31, 2011	$ 39,000
Warrants issued in connection with loan and security agreement	24,250
Change in fair value of warrant liability	(7,250)

Balance at December 31, 2012	56,000
Warrants issued in connection with loan and security agreement	49,000
Change in fair value of warrant liability	82,000
Reclassification to additional paid-in capital upon closing of IPO	(187,000)
Balance at September 30, 2013	$

4. Debt

In June 2012, the Company entered into a $3.0 million loan and security agreement collateralized by the Company s personal property. Interest on advances under the agreement is at a fixed interest rate equal to 4.50%. The loan and security agreement contains only non-financial covenants. Advances under the loan and security agreement have an interest-only period through December 31, 2013 and a 24-month payback period commences in January 2014.

As of September 30, 2013 and December 31, 2012, the Company had $0 and $2.0 million, respectively, in available credit under the loan and security agreement. Total interest incurred under the loan and security agreement for the three months ended September 30, 2013 and 2012 and the nine months ended September 30, 2013 and 2012 (excluding amortization of debt discount) was $34,125, $8,500, $102,125 and $8,500, respectively.

In connection with the loan and security agreement, a warrant was issued for shares of Series A Convertible Preferred Stock that is exercisable in whole, or in part, at any time until the expiration date of June 1, 2022. During July 2012, the Company drew down $1.0 million under the loan and security agreement and the warrant became exercisable for 4,000 shares of Series A Convertible Preferred Stock at an exercise price of $7.50 per share. During January 2013, the Company drew down the remaining $2.0 million under the loan and security agreement and the warrant became exercisable for an additional 8,000 shares of Series A Convertible Preferred Stock at an exercise price of $7.50 per share. Upon the closing of the Company s IPO in September 2013, the warrant became exercisable for 12,000 shares of common stock at an exercise price of $7.50 per share.

The initial $24,250 fair value of the 4,000 warrant shares earned in July 2012 and the initial $49,000 fair value of the 8,000 warrant shares earned in January 2013 were recorded as a debt discount and are amortized to interest expense over the term of the loan using the effective interest method. As of September 30, 2013 and December 31, 2012, the Company had unamortized debt discount of $51,762 and $20,208, respectively, related to the initial fair value of the warrants.

The initial fair value of warrants earned in 2012 and 2013 was estimated using the Black-Scholes option pricing model with the following assumptions:

	July 2012	January 2013
Assumed risk-free interest rate	1.43%	1.86%
Assumed volatility	80%	80%
Expected warrant life	10 years	9.5 years
Expected dividend yield	0.0%	0.0%

The aggregate advances under the Company s loan and security agreement and unamortized discount as of September 30, 2013 and December 31, 2012 are as follows:

	September 30, 2013	December 31, 2012
Aggregate advances under loan and security agreement	$ 3,000,000	$ 1,000,000
Less unamortized discount	(51,762)	(20,208)
Total debt, net of debt discount	2,948,238	979,792
	(1,069,802)	

Current portion of long-term debt, net of current portion of unamortized discount		
Long-term debt, net of current portion	$ 1,878,436	$ 979,792

5. Stock-based compensation

Stock-based payments to employees, including grants of employee stock options and restricted stock, are recognized in the financial statements based on their grant date fair values in accordance with the applicable accounting guidance. The compensation expense related to the Company s stock-based compensation arrangements has been included in the condensed statements of operations and comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
General and administrative	$ 7,316	$ 626	$ 9,504	$ 1,876
Research and development	313	2,500	4,377	7,502
Total share-based compensation expense	$ 7,629	$ 3,126	$ 13,881	$ 9,378

The fair value of equity instruments that are ultimately expected to vest, net of estimated forfeitures, are recognized and amortized on a straight-line basis over the requisite service period. The Company estimates forfeiture rates for equity awards based on past behavior for similar equity awards with further consideration given to the class of employees to whom the equity awards were granted.

As of September 30, 2013, total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was $833,751, which is expected to be recognized over a weighted average period of approximately 1.52 years.

The Company grants stock options to purchase common stock to employees with exercise prices equal to the value of the underlying stock, as determined by the board of directors on the date the equity award was granted. The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model using the appropriate forfeiture rate, risk-free interest rate, expected term and volatility assumptions. The expected life of the options was calculated using the simplified method, which calculates the life as the average of the contractual term and the vesting period of the option. Due to the Company s limited historical data as a public company, the estimated volatility was calculated based upon the historical volatility of comparable companies whose share prices are publicly available for a sufficient period of time. The risk-free interest rate was based upon the rates for U.S. Treasury securities with maturities similar to those of the expected term of the award being valued. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

Stock Option Assumptions

The Company granted stock options under the 2013 Equity Incentive Award Plan to purchase 108,000 and 0 shares of the Company s common stock during the nine months ended September 30, 2013 and 2012, respectively. The Company granted 108,000 stock options during the three months ended September 30, 2013. These stock options vest annually over a three-year period. The exercise price of all stock options granted during the nine months ended September 30, 2013 and 2012 was equal to the closing price of the Company s common stock on the date of grant. The estimated fair value of each stock option granted was determined on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions for the stock option grants:

	Three and Nine Months

	Ended September 30,	
	2013	**2012**
Risk-free interest rate	1.75%	
Expected volatility of common stock	71%	
Dividend yield	0.0%	
Expected option term	6 years	

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

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2012 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our final prospectus filed by us with the Securities and Exchange Commission, or SEC, on September 25, 2013 relating to our Registration Statement on Form S-1/A (File No. 333-188838) for our initial public offering.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statement. In some cases, you can identify forward-looking statements by terms such as may, will, should, expect, plan, anticipate, could, in project, contemplates, believes, estimates, predicts, potential or continue or the negative of these terms or expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. As a result of many factors, including without limitation those set forth under Risk Factors under Item 1A of Part II below, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. Except as required by applicable law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

Overview

We are a specialty pharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. We are developing EVK-001, a metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women with diabetes mellitus. Diabetic gastroparesis is a GI disorder afflicting millions of sufferers worldwide, in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms. Metoclopramide is the only product currently approved in the United States to treat gastroparesis, and is currently available only in oral and intravenous forms. EVK-001 is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through intranasal administration.

We have evaluated EVK-001 in a multicenter, randomized, double-blind, placebo-controlled parallel group, dose-ranging Phase 2b clinical trial in 287 patients with diabetic gastroparesis where EVK-001 was observed to be effective in improving the most prevalent and clinically relevant symptoms associated with gastroparesis in women while exhibiting a favorable safety profile. We plan to initiate a Phase 3 trial of EVK-001 in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in the first half of 2014.

We have no products approved for sale, and we have not generated any revenue from product sales or other arrangements. We have primarily funded our operations through the sale of our convertible preferred stock and borrowings under our loan and security agreements. We have incurred losses in each year since our inception. Substantially all of our operating losses resulted from expenses incurred in connection with advancing EVK-001

through development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

Questcor Asset Purchase Agreement

We acquired all worldwide rights, data, patents and other related assets associated with EVK-001 from Questcor Pharmaceuticals in June 2007. We paid to Questcor $650,000 in the form of an upfront payment, and will be required to make additional milestone payments totaling up to $52.0 million. These milestones include up to $5.0 million in payments if EVK-001 achieves the following development targets:

- $0.5 million upon the initiation of the first patient dosing in our planned Phase 3 clinical trial for EVK-001;
- $1.5 million upon the U.S. Food and Drug Administration s, or FDA s, acceptance for review of a new drug application, or NDA, for EVK-001; and
- $3.0 million upon the FDA s approval of EVK-001.

The remaining $47.0 million in milestone payments depend on EVK-001 s commercial success and will only apply if EVK-001 receives regulatory approval. In addition, we will be required to pay to Questcor a low single digit royalty on net sales of EVK-001. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering EVK-001, which is expected to occur in 2030.

Initial Public Offering and Related Transactions

On September 30, 2013, we completed our initial public offering, or IPO, whereby we sold 2,100,000 shares of common stock at $12.00 per share. Net proceeds from the IPO were determined as follows:

Gross proceeds (excluding over-allotment)	$ 25,200,000
Underwriting discounts and commissions and non-accountable expense allowance	(2,080,275)
Total offering costs (excluding value of warrants granted to underwriter of $470,000)	(1,444,043)
Net proceeds	$ 21,675,682

Additionally, upon the closing of the IPO, certain transactions occurred based on a successful completion of the IPO:

- the conversion of all outstanding shares of convertible preferred stock into 2,439,002 shares of our common stock;
- retention bonuses in the amount of $355,000 became payable to our executive officers. Such amount will be recorded as expense on a straight-line basis from May 22, 2013 (the date of the Retention Agreements) through December 24, 2013, the date at which the final payment is due based on continued employment. Since the terms of the payment required the occurrence of either a change in control of the Company, or an equity financing, neither of which are considered probable to occur until they happen, a catch-up expense of $202,857 was recorded at the time of our IPO. Should the executive officers voluntarily terminate their employment, or are terminated by us for cause, the executive would forfeit any portion of the retention

payment that has not been paid to them;

the issuance of warrants to purchase 84,000 shares of our common stock to the representative of the underwriters of our IPO and certain of its affiliates. The warrants will become exercisable at a price of $21.00 per share beginning on September 24, 2014 and will expire on September 24, 2018. The initial fair value of the warrants of $470,000 was determined using the Black-Scholes option pricing model on the date of the IPO and recorded as a cost of the issuance of common stock from our IPO and charged to additional paid-in capital;

the conversion of warrants to purchase 110,000 shares of convertible preferred stock into warrants to purchase 22,000 shares of our common stock and the resultant reclassification of the $187,000 warrant liability to additional paid-in capital; and

the filing of an amended and restated certificate of incorporation to authorize 50,000,000 shares of common stock and 5,000,000 shares of undesignated preferred stock.

Financial Operations Overview

Research and Development Expenses

We expense all research and development expenses as they are incurred. Research and development expenses primarily include:

- clinical trial and regulatory-related costs;
- expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants that conduct our clinical trials;
- manufacturing and stability testing costs and related supplies and materials; and
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense.

All of our research and development expenses to date have been incurred in connection with EVK-001. We expect our research and development expenses to increase for the foreseeable future as we advance EVK-001 through clinical development, including the conduct of our planned Phase 3 clinical trial. The Phase 3 clinical trial is currently expected to initiate in the first half of 2014. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We are unable to estimate with any certainty the costs we will incur in the continued development of EVK-001. However, we currently estimate the costs to complete our Phase 3 clinical trial in women, our companion clinical trial in men and a thorough QT study of EVK-001 will be approximately $15.0 million. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We may never succeed in achieving marketing approval for our product candidate.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;

the cost of comparative agents used in trials;

the drop-out or discontinuation rates of patients;

potential additional safety monitoring or other studies requested by regulatory agencies;

the duration of patient follow-up; and

the efficacy and safety profile of the product candidate.

We do not expect EVK-001 to be commercially available, if at all, for the next few years.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation. Our general and administrative expenses primarily consisted of payroll expenses for our two full-time employees. Other general and administrative expenses include professional fees for auditing, tax, patent costs and legal services.

We expect that general and administrative expenses will increase in the future as we expand our operating activities and incur additional costs associated with being a publicly-traded company and maintaining compliance with exchange listing and Securities and Exchange Commission requirements. These increases will likely include higher employee compensation costs due to additional staff, higher consulting costs, legal fees, accounting fees, directors and officers liability insurance premiums and fees associated with investor relations.

Total Other Income (Expense)

Total other income (expense) consists primarily of interest income we earn on interest-bearing accounts and money market funds for cash and cash equivalents, interest expense incurred and the amortization of debt discount on our outstanding debt and changes in the fair value of our warrant liability and preferred stock purchase right liability.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States (GAAP). 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 expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. 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. Our actual results may differ materially from these estimates under different assumptions or conditions.

We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity within Note 2 to our audited financial statements, which are contained in our final prospectus filed with the SEC on September 25, 2013 relating to our Registration Statement on Form S-1/A (File No. 333-188838) for our IPO. Except for the estimate of stock-based compensation expense related to the issuance of stock options in September 2013, there have been no material changes to our critical accounting policies and estimates as disclosed in our Registration Statement on Form S-1 (File No. 333-188838).

Results of Operations

Comparison of the Three Months Ended September 30, 2013 and 2012

The following table summarizes the results of our operations for the three months ended September 30, 2013 and 2012:

	Three Months Ended September 30,		Increase /
	2013	2012	(Decrease)
Research and development	$ 78,731	$ 337,003	$ (258,272)
General and administrative	406,862	140,746	266,116
Total other income (expense), net	(311)	(8,505)	8,194

Research and Development Expenses. Research and development expenses were approximately $79,000 for the three months ended September 30, 2013, compared to approximately $337,000 for the three months ended September 30, 2012. The decrease of approximately $258,000 was primarily related to the decrease in clinical development-related costs as a larger portion of our labor cost was allocated to general and administrative time in 2013 in preparation for our initial public offering.

General and Administrative Expenses. General and administrative expenses were approximately $407,000 for the three months ended September 30, 2013, compared to approximately $141,000 for the three months ended September 30, 2012. The increase of approximately $266,000 is primarily related to a larger portion of our labor cost being allocated to general and administrative activities in 2013 in preparation for our initial public offering.

Other Income (Expense). Net other income (expense) was $(311) for the three months ended September 30, 2013 and primarily consisted of interest expense of approximately $(40,000) and an adjustment of 39,000 to the fair value of our warrant liability. Other income (expense) was $(8,505) for the three months ended September 30, 2012 and primarily consisted of interest expense of approximately $(10,500) and an adjustment to the fair value of our warrant liability of approximately $1,600.

Comparison of the Nine Months Ended September 30, 2013 and 2012

The following table summarizes the results of our operations for the nine months ended September 30, 2013 and 2012:

	Nine Months Ended September 30,		Increase / (Decrease)
	2013	2012	
Research and development	$ 320,558	$ 847,298	$ (526,740)
General and administrative	700,489	493,210	207,279
Total other income (expense), net	(198,720)	(4,570)	(194,150)

Research and Development Expenses. Research and development expenses were approximately $321,000 for the nine months ended September 30, 2013, compared to approximately $847,000 for the nine months ended September 30, 2012. The decrease of approximately $526,000 is primarily related to the reduction of clinical development costs as we completed the Phase 2 clinical trial for EVK001, the decrease in executive compensation allocated to research and development as we worked to raise capital, and the election by our board of directors in May 2013 to not pay 2012 bonuses.

General and Administrative Expenses. General and administrative expenses were approximately $700,000 for the nine months ended September 30, 2013, compared to approximately $493,000 for the nine months ended September 30, 2012. The increase of approximately $207,000 is primarily related to a larger portion of our labor cost being allocated to general and administrative activities in 2013 in preparation for our initial public offering, the accrual for the executive team s retention payment, and offset by the reversal of the 2012 bonus accrual due to the election by of board of directors in April 2013 to not pay 2012 bonuses.

Other Income (Expense). Other income (expense) was approximately $(199,000) for the nine months ended September 30, 2013 and primarily consisted of interest expense of approximately $(120,000) related to advances under our loan and security agreement and an adjustment of $(82,000) to the fair value of our warrant liability. Other income (expense) was approximately $(4,600) for the nine months ended September 30, 2012 and primarily consisted of interest expense of approximately $(10,500) related to advances under our loan and security agreement offset by adjustments of approximately $(4,600) to the fair value of our outstanding warrant liability.

Liquidity and Capital Resources

We have funded our operations primarily from the sale of equity securities and borrowings under our loan and security agreements. We have incurred losses since inception and negative cash flows from operating activities. As of September 30, 2013, including the net proceeds from our IPO, we had approximately $23.7 million in cash and cash equivalents. On October 8, 2013, the underwriters for our IPO exercised their over-allotment option to purchase an additional 315,000 shares of our common stock at $12.00 per share. The over-allotment exercise is expected to result in estimated net proceeds to the Company of $3,440,400, after deducting $264,600 of underwriting discounts and commissions and an estimated $75,000 of additional offering costs.

In June 2012, we entered into a $3.0 million loan and security agreement with Silicon Valley Bank which is collateralized by our personal property. Interest on advances under the agreement is at a fixed interest rate equal to 4.50%. The loan and security agreement contains only non-financial covenants. Advances under the loan and security agreement have an interest-only period through December 31, 2013 and a 24-month payback period commences in January 2014. As of January 2, 2013, we had drawn down the entire $3.0 million available under the agreement to fund working capital and have no credit available for future borrowings.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. In the near-term, we anticipate that our expenses will increase substantially as we:

- initiate significant clinical trials associated with EVK-001, including our planned Phase 3 clinical trial that we plan to initiate in the first half of 2014;
- hire additional staff, including clinical, scientific, operational, financial and management personnel; and
- to maintain, expand and protect our intellectual property portfolio.

To fund further operations we will need to raise additional capital. Our current cash and cash equivalents, which include the proceeds from our IPO, may not be sufficient for us to complete our planned Phase 3 clinical trial of EVK-001 or any additional development requirements requested by the FDA, and will not be sufficient to submit marketing applications for and prepare for commercialization of EVK-001 should we receive product approval. At this time, due to the risks inherent in the drug development process, we are unable to estimate with any certainty the costs we will incur in the continued development of EVK-001 for potential commercialization. However, we currently estimate the costs to complete our Phase 3 clinical trial in women, our companion clinical trial in men and a thorough QT study of EVK-001 will be approximately $15.0 million. Accordingly, we may require substantial additional capital to continue our clinical development and will require substantial additional capital for potential commercialization activities. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources, such as potential collaboration arrangements. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies.

The following table sets forth a summary of the net cash flow activity for each of the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2013	**2012**
Net cash used in operating activities	$ (1,151,002)	$ (1,097,104)
Net cash used in investing activities		
Net cash provided by financing activities	24,773,042	1,000,000
Net change in cash and cash equivalents	$ 23,622,040	$ (97,104)

Operating Activities. Net cash used in operating activities was approximately $1.2 million for the nine months ended September 30, 2013, compared to net cash used in operating activities of $1.1 million for the nine months ended September 30, 2012. In all periods the primary use of cash was to fund our net loss.

Financing Activities. Net cash provided by financing activities was $24.8 million for the nine months ended September 30, 2013 compared to net cash provided by financing activities of $1.0 million for the nine months ended September 30, 2012. During the nine months ended September 30, 2013 our financing activity consisted of a $2.0 million draw under our loan and security agreement to fund working capital requirements and the net proceeds of approximately $22.8 million from our IPO. Approximately $1.1 of additional IPO costs incurred in the nine months ended September 30, 2013 were paid in October 2013. During the nine months ended September 30, 2012 our financing activity was a $1.0 million draw under our loan and security agreement to fund working capital requirements.

We believe that our existing cash and cash equivalents as of September 30, 2013, together with interest thereon, and the estimated net proceeds of $3.4 million from the exercise of the underwriter over-allotment in October 2013, will be sufficient to meet our anticipated cash requirements for approximately the next 18 months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

the initiation, progress, costs, results of and timing of our clinical development program for EVK-001, including our planned Phase 3 clinical trial;

the need for, and the progress, costs and results of, any additional clinical trials of EVK-001 we may initiate based on the results of our planned clinical trials or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of EVK-001;

the outcome, costs and timing of seeking and obtaining regulatory approvals from the FDA, and any similar regulatory agencies;

the timing and costs associated with manufacturing EVK-001 for clinical trials and other studies and, if approved, for commercial sale;

our need and ability to hire additional management, development and scientific personnel;

the cost to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

the timing and costs associated with establishing sales and marketing capabilities;

market acceptance of EVK-001;

the extent to which we are required to pay milestone or other payments under our Questcor asset purchase agreement and the timing of such payments;

the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and

our need to implement additional internal systems and infrastructure, including financial and reporting systems.

Contractual Obligations

Our most significant clinical trial expenditures are to CROs. The contracts with CROs generally are cancellable, with notice, at our option and do not have any cancellation penalties.

Our long-term debt obligation consists of amounts we are obligated to repay under our loan and security agreement with Silicon Valley Bank, of which we have drawn the full amount of $3.0 million as of January 2, 2013. Unless principal is paid in advance, we are required to make an aggregate of $135,000 of interest-only payments in 2013. In January 2014 we are required to begin making the first of 24 monthly principal and interest payments of $131,024, such that the loan balance will be fully repaid in December 2015. We will incur a total of $144,570 of interest charges in 2014 and 2015.

As of September 30, 2013 and December 31, 2012, we had no operating lease commitments.

Off-Balance Sheet Arrangements

Through September 30, 2013, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Fluctuation Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of our cash and cash equivalents, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations.

Our long-term debt bears interest at a fixed rate and therefore has minimal exposure to changes in interest rates.

Foreign Currency Exchange Risk

To date, all of our contractual obligations have been denominated in U.S. dollars. In the future, we may contract with organizations to manufacture drug product, active pharmaceutical ingredient, container closure system materials as well as CROs and investigational sites in foreign countries. We may therefore become subject to fluctuations in foreign currency rates in connection with these agreements.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief business officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of September 30, 2013, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief business officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our chief executive officer and chief business officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2013.

No change in our internal control over financial reporting, as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act, occurred during the three months ended September 30, 2013 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 currently not a party to any material legal proceedings.

Item 1A. Risk Factors

You should carefully consider the following risk factors, together with the other information in this Quarterly Report on Form 10-Q and in our final prospectus filed with the Securities and Exchange Commission, or SEC, on September 25, 2013, relating to our Registration Statement on Form S-1/A (File No. 333-188838), for our initial public offering including our financial statements and the related notes appearing at the end of our final prospectus, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that reflect substantive changes from the risk factors included in our final prospectus.

Risks Related to our Business, including the Development, Regulatory Approval and Potential Commercialization of our Product Candidate, EVK-001

Our business is entirely dependent on the success of a single product candidate, EVK-001, which has not yet entered a Phase 3 clinical trial. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, EVK-001.*

We have only one product candidate: EVK-001, a metoclopramide nasal spray to treat female patients with symptoms associated with acute and recurrent diabetic gastroparesis. We are entirely dependent on successful continued development and regulatory approval of this product candidate for our future business success. We have invested, and will continue to invest, a significant portion of our time and financial resources in the development of EVK-001. We will need to successfully enroll and complete our planned Phase 3 clinical trial of EVK-001, which we intend to commence in the first half of 2014, and, if required, raise sufficient funds for the completion of this trial. The future regulatory and commercial success of this product candidate is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the Phase 3 clinical trial;
- we may not be able to provide acceptable evidence of safety and efficacy for EVK-001;
- the results of our planned clinical trials may not confirm the positive results of earlier clinical trials, particularly because we will utilize a modified patient report outcomes, or PRO, instrument for our planned Phase 3 clinical trial compared to our Phase 2b clinical trial;

variability in patients, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;

the results of our clinical trial may not meet the level of statistical or clinical significance required by the FDA, for marketing approval;

we may be required to undertake additional clinical trials and other studies of EVK-001 before we can submit a NDA, to the FDA or receive approval of the NDA;

patients in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to EVK-001, such as dysgeusia, headache, diarrhea, nasal discomfort, tremor, myoclonus, somnolence, rhinorrhea, throat irritation, and fatigue;

if approved, EVK-001 will compete with well-established products already approved for marketing by the FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for EVK-001;

we may not be able to obtain, maintain and enforce our patents and other intellectual property rights; and

we may not be able to obtain and maintain commercial manufacturing arrangements with third-party manufacturers or establish commercial-scale manufacturing capabilities.

Of the large number of drugs in development in this industry, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market EVK-001, any such approval may be subject to limitations on the indicated uses for which we may market the product.

We will require substantial additional funding and may be unable to raise capital when needed, which would force us to suspend our Phase 3 clinical trial and otherwise delay, reduce or eliminate our development program for EVK-001.*

Our operations have consumed substantial amounts of cash since inception. To date, our operations have been primarily financed through the proceeds from the sale of our common and preferred stock, and borrowings under our loan and financing agreements with Silicon Valley Bank and a prior lender. We believe, based on our current operating plan, that the net proceeds from our initial public offering and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations for approximately the next 18 months although there can be no assurance in that regard. Because we expect our planned Phase 3 clinical trial of EVK-001 to commence in the first half of 2014 with an approximately 12 month enrollment period, we may need to obtain additional funds to complete this trial as well as finance any additional development requirements requested by the FDA.

Our estimates of the amount of cash necessary to fund our activities may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

the rate of progress and cost of our Phase 3 clinical trial and any other clinical requirements for EVK-001;

the timing of regulatory approval, if granted, of EVK-001 or any other product candidates;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with EVK-001;

the costs and timing of completion of outsourced commercial manufacturing supply arrangements for EVK-001;

costs associated with any other product candidates that we may develop, in-license or acquire;

the effect of competing technological and market developments; and

the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish.

The results observed in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in our Phase 2b clinical trial of EVK-001 may not be predictive of the safety and efficacy results in our planned Phase 3 clinical trial.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in earlier-stage development. We currently plan to commence one Phase 3 clinical trial in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in the first half of 2014. Our Phase 2b clinical trial of EVK-001 for the treatment of diabetic gastroparesis showed statistically significant improvement in clinically meaningful endpoints in female patients. This was a pre-specified analyses of the primary efficacy endpoint performed on a gender subgroup of the intent to treat, or ITT population. Due to a large placebo response in male patients, EVK-001 did not achieve the primary endpoint in the ITT population for all subjects in this Phase 2b clinical trial.

This risk may be particularly significant for us because the primary endpoint in our planned Phase 3 clinical trial is not identical to the primary endpoint used in our Phase 2b trial. In our Phase 2b clinical trial, the primary endpoint was the Gastroparesis Cardinal Symptom Index Daily Diary, or GCSI-DD, a PRO instrument. The GCSI-DD is a composite of clinically relevant diabetic gastroparesis symptoms which patients rate according to severity. Based on our discussions with the FDA, the primary endpoint for our Phase 3 trial will be the Gastroparesis Symptom Assessment, or GSA, which is a PRO instrument derived from the GCSI-DD. We have analyzed our

Phase 2b data utilizing the GSA s methodology. Although we observed statistically significant and nearly identical statistical improvement in the GSA compared to the GCSI-DD in females in our Phase 2b trial, we cannot assure you that our Phase 3 trials will achieve positive results.

A number of factors could contribute to a lack of favorable safety and efficacy results in our planned Phase 3 trial. For example:

- a multicenter trial could result in increased variability due to varying site characteristics, such as local standards of care;
- a multicenter trial could result in increased variability due to varying patient characteristics including demographic factors, health status, underlying reason for disease state and concomitant medications; and
- diagnosis of diabetic gastroparesis by physicians, including use of gastric emptying tests, could select for a patient population that differs from those patients included within previous clinical trials.

If we are not able to obtain regulatory approval for EVK-001, we will not be able to commercialize this product candidate and our ability to generate revenue will be limited.

We have not submitted an NDA or received regulatory approval to market any product candidates in any jurisdiction. We are not permitted to market EVK-001 in the United States until we receive approval of an NDA for the product candidate in a particular indication from the FDA. To date, we have completed one Phase 2 clinical trial for EVK-001 in diabetic subjects with gastroparesis and acquired the results from a separate Phase 2 clinical trial in diabetic patients with gastroparesis. In the Phase 2 clinical trial that we performed ourselves, which concluded in 2011, EVK-001 failed to meet the primary endpoint for the trial. Although an overall improvement in symptoms was observed in EVK-001-treated patients with diabetic gastroparesis compared to placebo in this second Phase 2 clinical trial, the difference was not statistically significant due to a high placebo response among male subjects. The earlier Phase 2 clinical trial performed by Questcor Pharmaceuticals, Inc., or Questcor, was a multicenter, randomized, open-label, parallel design study. This head-to-head study compared the efficacy and safety of two doses of metoclopramide nasal spray, 10 mg and 20 mg, with the FDA-approved 10 mg metoclopramide tablet. Although data from the earlier Phase 2 clinical trial will be referenced in the EVK-001 NDA, the open-label study design limits the importance of the efficacy results in the NDA.

We currently plan to commence one Phase 3 clinical trial in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in the first half of 2014. There is no guarantee that this Phase 3 clinical trial or any other future trials will be successful or that regulators will agree with our assessment of the clinical trials for EVK-001 conducted to date. In addition, we have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations to assist us in this process. The FDA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or preclinical or other studies.

Varying interpretation of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, we have acquired our rights to EVK-001 from Questcor who acquired its rights from a predecessor. Thus, much of the preclinical and a portion of the clinical data relating to EVK-001 that we would expect to submit in an NDA for EVK-001 was obtained from studies conducted before we owned the rights to the product candidate and, accordingly, was prepared and managed by others. These predecessors may not have

applied the same resources and given the same attention to this development program as we would have if we had been in control from inception.

EVK-001 and the activities associated with its development and potential commercialization, including its testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory marketing approval for EVK-001 will prevent us from commercializing the product candidate, and our ability to generate revenue will be materially impaired.

The FDA may impose requirements on our clinical trials that are difficult to comply with, which could harm our business.

The requirements that the FDA may impose on clinical trials for EVK-001 are uncertain. We currently plan to conduct one Phase 3 trial in adult female subjects with diabetic gastroparesis, which we believe will be sufficient for NDA submission. We plan to initiate the four-week, multicenter, randomized, double-blind, placebo-controlled, parallel Phase 3 clinical trial to evaluate the efficacy, safety and population pharmacokinetics of EVK-001 in adult female subjects with diabetic gastroparesis in the first half of 2014. Although we believe successful results from this single Phase 3 clinical trial will be sufficient to allow us to submit an NDA for EVK-001, it is possible the FDA will require additional clinical testing before submission or approval of the NDA. In addition, based on discussions with the FDA, we also plan to conduct a similar study for safety and efficacy in adult male subjects with diabetic gastroparesis. If we are unable to comply with the FDA s requirements, we will not be able to obtain approval for EVK-001 and our business will suffer.

Any termination or suspension of, or delays in the commencement or completion of, our planned Phase 3 clinical trial could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Delays in the commencement or completion of our planned Phase 3 clinical trial for EVK-001 could significantly affect our product development costs. We do not know whether our planned trial will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA failing to grant permission to proceed and placing the clinical trial on hold;
- subjects failing to enroll or remain in our trial at the rate we expect;
- subjects choosing an alternative treatment for the indication for which we are developing EVK-001, or participating in competing clinical trials;
- subjects experiencing severe or unexpected drug-related adverse effects;
- a facility manufacturing EVK-001 or any of its components being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of current Good Manufacturing Practices, or cGMP, or other applicable requirements, or infections or cross-contaminations of product candidate in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, Good Clinical Practice and regulatory requirements, or other third parties not

performing data collection and analysis in a timely or accurate manner;

inspections of clinical trial sites by the FDA or the finding of regulatory violations by the FDA or an institutional review board, or IRB, that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;

third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications; or

one or more IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial.

Product development costs will increase if we have delays in testing or approval of EVK-001 or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical trial sites suspend or terminate any of our clinical trials, the commercial prospects for our product candidate may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Also if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of EVK-001 could be significantly reduced.

Final marketing approval for EVK-001 by the FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

After the completion of our Phase 3 clinical trial and, assuming the results of the trial are successful, the submission of an NDA, we cannot predict whether or when we will obtain regulatory approval to commercialize EVK-001 and we cannot, therefore, predict the timing of any future revenue. Because EVK-001 is our only product candidate this risk is particularly significant for us. We cannot commercialize EVK-001 until the appropriate regulatory authorities have reviewed and approved the applications for this product candidate. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for EVK-001. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. For example, the FDA reviewed metoclopramide spontaneous safety reports and, in 2009, required a boxed warning be added to the metoclopramide product label concerning the chance of tardive dyskinesia, or TD, for patients taking these products. Recently, the European Medicines Agency s Committee on Medicinal Products for Human Use, or CHMP, has reviewed and has proposed labeling changes for marketed metoclopramide products in the European Union based on age, dosing guidelines or indications. Based on their assessment of the limited efficacy and safety data currently available to the CHMP, the CHMP recommended to the European Medicines Agency that indications with limited or inconclusive efficacy data, including GERD, dyspepsia and gastroparesis, be removed from the approved product label in the European Union. There can be no assurance as to whether the FDA will re-review approved metoclopramide product labels as a result of any such regulatory actions in the European Union or otherwise. If marketing approval for EVK-001 is delayed, limited or denied, our ability to market the product candidate, and our ability to generate product sales, would be adversely affected.

Even if we obtain marketing approval for EVK-001, it could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidate, when and if EVK-001 is approved.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on EVK-001 s indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials. EVK-001 will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we or the manufacturing facilities for EVK-001 fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;

- seek an injunction or impose civil or criminal penalties or monetary fines;

suspend or withdraw regulatory approval;

suspend any ongoing clinical trials;

refuse to approve pending applications or supplements or applications filed by us;

suspend or impose restrictions on operations, including costly new manufacturing requirements; or

seize or detain products, refuse to permit the import or export of product, or request us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

The FDA has the authority to require a risk evaluation and mitigation strategy plan as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. In March 2009, the FDA informed drug manufacturers that it will require a REMS for metoclopramide drug products. The FDA s authority to take this action is based on risk management and post market safety provisions within the Food and Drug Administration Amendments Act. The REMS consists of a Medication Guide, elements to assure safe use (including an education program for prescribers and materials for prescribers to educate patients), and a timetable for submission of assessments of at least six months, 12 months, and annually after the REMS is approved. We intend to submit a REMS at the time of the NDA submission for EVK-001.

In addition, if EVK-001 is approved, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product s approved labeling. If we receive marketing approval for EVK-001, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Even if we receive regulatory approval for EVK-001, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, will be limited.

EVK-001 s commercial success will depend upon the acceptance of the product candidate by the medical community, including physicians, patients and health care payors. The degree of market acceptance of our product candidate will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the limitation of our targeted patient population to women-only;
- limitations or warnings contained in any FDA-approved labeling, including the potential boxed warning on all metoclopramide product labels concerning the chance of TD for patients taking these products, or any limitations with respect to metoclopramide product labels in the European Union;
- acceptance of a new formulation by health care providers and their patients;
- the prevalence and severity of any adverse effects;

new procedures or methods of treatment that may be more effective in treating or may reduce the incidences of diabetic gastroparesis;

pricing and cost-effectiveness;

the effectiveness of our or any future collaborators sales and marketing strategies;

our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and

the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If EVK-001 is approved, but does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue, and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of EVK-001 may require significant resources and may never be successful. In addition, our ability to successfully commercialize our product candidate will depend on our ability to manufacture our products, differentiate our products from competing products and defend the intellectual property of our products.

It will be difficult for us to profitably sell EVK-001 if reimbursement is limited.

Market acceptance and sales of our product candidate will depend on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors have been challenging the prices charged for products. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted marketing approval. This trend may impact the reimbursement for treatments for GI disorders especially, including EVK-001, as physicians typically focus on symptoms rather than underlying conditions when treating patients with these disorders and drugs are often prescribed for uses outside of their approved indications. In instances where alternative products are available, it may be required that those alternative treatment options are tried before reimbursement is available for EVK-001. Although EVK-001 is a novel nasal spray formulation of metoclopramide, this is the same active ingredient that is already available in other treatments for gastroparesis that are already widely available at generic prices. We cannot be sure that reimbursement will be available for our EVK-001 and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, this product candidate. In addition, in certain foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize our product candidate.

We rely and will continue to rely on outsourcing arrangements for many of our activities, including clinical development and supply of EVK-001.

We have only two full-time employees and, as a result, we rely on outsourcing arrangements for a significant portion of our activities, including clinical research, data collection and analysis and manufacturing as well as function as a public company. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

We expect to retain a contract research organization, or CRO, to conduct our planned Phase 3 clinical trial of EVK-001. We will be required to reach agreement on acceptable terms with prospective CROs as well as clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites. We will need assistance from our CRO in obtaining IRB approval at each clinical trial site and will rely on our CRO to recruiting suitable patients to participate the proposed trial.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We do not own or operate manufacturing facilities for the production of any component of EVK-001, including metoclopramide, the nasal spray device or associated bottle, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and drug product for our clinical trials. For EVK-001, we are currently using, and relying on, single suppliers and single manufacturers for starting materials, the final drug substance and nasal spray delivery device. Although potential alternative suppliers and manufacturers for some components have been identified, we have not qualified these vendors to date. If we were required to change vendors, it could result in a failure to meet regulatory requirements or projected timelines and necessary quality standards for successful manufacturing of the various required lots of material for our development and commercialization efforts.

We do not have any current contractual relationships for the manufacture of commercial supplies of EVK-001. If EVK-001 is approved for sale by any regulatory agency, we intend to enter into agreements with third-party contract

manufacturers for commercial production. The number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture bulk drug substance on a commercial scale is limited. We have identified one manufacturer for potentially providing commercial supplies of EVK-001; however no alternative providers have been identified to date. If we are unable to come to terms on commercial supplier with this manufacturer, we would have to find replacements, which could delay the commercialization of our product candidate.

In addition, our reliance on third party CROs and contract manufacturing organizations, or CMOs, entails further risks including:

non-compliance by third parties with regulatory and quality control standards;

breach by third parties of our agreements with them;

termination or non-renewal of an agreement with third parties; and

sanctions imposed by regulatory authorities if compounds supplied or manufactured by a third party supplier or manufacturer fail to comply with applicable regulatory standards.

We face substantial competition, which may result in others selling their products more effectively than we do, and in others discovering, developing or commercializing product candidates before, or more successfully, than we do.

Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of EVK-001. We anticipate that EVK-001, if approved, would compete directly with metoclopramide, erythromycin and domperidone, each of which is available under various trade names sold by several major pharmaceutical companies, including generic manufacturers. Metoclopramide is the only molecule currently approved in the United States to treat gastroparesis. Metoclopramide is generically-available and indicated for the relief of symptoms associated with acute and recurrent diabetic gastroparesis, without the limitation of use in women only.

Many of our potential competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial infrastructures than we have. We will not be able to compete successfully unless we successfully:

assure health care providers, patients and health care payors that EVK-001 is beneficial compared to other products in the market;

obtain patent and/or other proprietary protection for EVK-001;

obtain and maintain required regulatory approvals for the product candidate; and

collaborate with others to effectively market, sell and distribute EVK-001.

Established competitors may invest heavily to quickly discover and develop novel compounds that could make our product candidate obsolete. In addition to our EVK-001 product candidate, we are aware of other development candidates in clinical development. Any of these product candidates could advance through clinical development faster than EVK-001 and, if approved, could attain faster and greater market acceptance than our product candidate. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

We have no sales, marketing or distribution capabilities currently and we will have to invest significant resources to develop these capabilities.

Currently, we have no internal sales, marketing or distribution capabilities. If EVK-001 ultimately receives regulatory approval, we may not be able to effectively market and distribute the product candidate. We will have to invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that EVK-001 will be approved. We may not

be able to hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms or at all. Even if we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- inability to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenues generated by EVK-001 or any other product candidates that we may develop, in-license or acquire; and
- our direct sales and marketing efforts may not be successful.

If we fail to attract and retain senior management and key commercial personnel, we may be unable to successfully complete the development of EVK-001 and commercialize this product candidate.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and commercial personnel. We are highly dependent upon our senior management team composed of two individuals: David Gonyer, our President and Chief Executive Officer, and Matt D Onofrio, our Executive Vice President and Chief Business Officer. The loss of services of either of these individuals could delay or prevent the successful development of EVK-001 or the commercialization of this product candidate, if approved.

We will need to hire and retain qualified personnel. We could experience problems in the future attracting and retaining qualified employees. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense, particularly in the San Diego, California area where we are headquartered. We may not be able to attract and retain quality personnel on acceptable terms who have the expertise we need to sustain and grow our business.

We may encounter difficulties in managing our growth and expanding our operations successfully.

Because we currently have only two full-time employees, we will need to grow our organization substantially to continue the development and pursue the potential commercialization of EVK-001. As we seek to advance EVK-001, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management and require us to retain additional internal capabilities. Our future financial performance and our ability to commercialize EVK-001 and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, clinical and regulatory, financial, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize EVK-001 and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for EVK-001, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidate, assuming we obtain marketing approval.

Legislative and regulatory proposals have been made 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 EVK-001, 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 testing and other requirements.

In the United States, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In early 2010, President Obama signed into law the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against 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. Effective October 1, 2010, the Health Care Reform Law revised the definition of average manufacturer price for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, beginning in 2011, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include false claims statutes and anti-kickback statutes. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines and imprisonment.

Federal legislation and actions by state and local governments may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results and our overall financial condition.

We may face competition in the United States for EVK-001, if approved, from lower priced products from foreign countries that have placed price controls on pharmaceutical products. This risk may be particularly applicable to drugs such as EVK-001. The MMA contains provisions that may change U.S. importation laws and expand pharmacists and wholesalers ability to import lower priced versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will pose no additional risk to the public s health and safety and will result in a significant reduction in the cost of products to consumers. The Secretary of Health and Human Services has not yet announced any plans to make this required certification.

A number of federal legislative proposals have been made to implement the changes to the U.S. importation laws without any certification, and to broaden permissible imports in other ways. Even if the changes do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, U.S. Customs and Border Protection and other

government agencies. For example, Pub. L. No. 111-83, which was signed into law in October 2009 and provides appropriations for the Department of Homeland Security for the 2010 fiscal year, expressly prohibits U.S. Customs and Border Protection from using funds to prevent individuals from importing from Canada less than a 90-day supply of a prescription drug for personal use, when the drug otherwise complies with the Federal Food, Drug, and Cosmetic Act, or FDCA. Further, several states and local governments have implemented importation schemes for their citizens and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts.

The importation of foreign products that compete with EVK-001 could negatively impact our revenue and profitability, possibly materially.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of EVK-001.

We face an inherent risk of product liability as a result of the clinical testing of EVK-001 and will face an even greater risk if we commercialize the product candidate. For example, we may be sued if EVK-001 allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts.

In particular, products containing metoclopramide have been reported to cause side effects, including TD. It is possible that a patient taking EVK-001 will be found to experience a variety of side effects. In 2009, the FDA required a boxed warning on all metoclopramide product labels concerning the chance of TD for patients taking these products. We expect that the label for EVK-001, if approved, will likely contain a similar warning regarding TD. Several manufactures of metoclopramide products have been sued by patients regarding TD.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidate. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

decreased demand for EVK-001;

injury to our reputation;

withdrawal of clinical trial participants;

costs to defend the related litigation;

a diversion of management s time and our resources;

substantial monetary awards to trial participants or patients;

product recalls, withdrawals or labeling, marketing or promotional restrictions;

loss of revenue;

the inability to commercialize EVK-001; and

a decline in our stock price.

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

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business, including for the continued development or commercialization of EVK-001. These relationships or those like them may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for EVK-001 because third parties may view the risk of success in our planned Phase 3 clinical trial as too significant or the commercial opportunity for our product candidate as too limited. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors and consultants and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development program for EVK-001 and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to

recover or reproduce the data. Likewise, we rely on third parties to manufacture EVK-001 and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidate could be delayed.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our EVK-001. Our ability to obtain clinical supplies of EVK-001 could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Our operations are located in San Diego, California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

If we fail to develop and commercialize other product candidates, we may be unable to grow our business.

As part of our growth strategy, we plan to evaluate the development and/or commercialization of other therapies for GI motility disorders. Similar to our initial focus on gastroparesis, we will evaluate opportunities to in-license or acquire other product candidates as well as commercial products to treat patients suffering from predominantly GI disorders, seeking to identify areas of high unmet medical needs with limited treatment options. These other product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, extensive clinical trials and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the drug candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time we have considered, and we will continue to consider in the future, strategic business initiatives intended to further the development of our business. These initiatives may include acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things:

issue equity securities that would dilute our current stockholders percentage ownership;

incur substantial debt that may place strains on our operations;

spend substantial operational, financial and management resources in integrating new businesses, technologies and products; and

assume substantial actual or contingent liabilities.

We may be unable to maintain sufficient product liability insurance.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any product, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Relating to Our Intellectual Property

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights. Any impairment of our intellectual property rights would materially affect our business.

We place considerable importance on obtaining patent protection for new technologies, products and processes because our commercial success will depend, in large part, on obtaining patent protection for new technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing our patents against third party competitors. To that end, we have acquired and will file applications for patents covering formulations containing or uses of EVK-001 or our proprietary processes as well as other intellectual property important to our business. One of our patents related to EVK-001 was acquired from Questcor. This method of use patent was not written by us or our attorneys, and we did not have control over the drafting and prosecution of these patents. Further, Questcor and other predecessors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patent and application and had control over the drafting and prosecution.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our predecessors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our predecessors were the first to file for patent protection of such inventions One or more of these factors could possibly result in findings of invalidity or unenforceability of one or more of the patents we own.

The patent rights we own covering EVK-001 are limited to specific methods of use and formulations of metoclopramide. As a result, our ability to market EVK-001 may be limited by the lack of patent protection for the active ingredient itself and other metoclopramide formulations may be developed by competitors. The active ingredient in EVK-001 is metoclopramide. No patent protection is available for metoclopramide itself. As a result, competitors who develop and receive required regulatory approval for competing products using the same active ingredient as EVK-001 may market their competing products so long as they do not infringe any of the method or formulation patents owned by us.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours, or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we will not be involved in interference, opposition or invalidity proceedings before U.S. or foreign patent offices.

We have focused our intellectual property efforts on the United States. To the extent that our patent portfolio differs from country to country outside the United States, this may make protecting EVK-001 as a product outside the United States even more difficult and unpredictable. Various countries maintain their own standards and interpretation of intellectual property law, potentially creating additional patent risk beyond even that experienced within the United States.

We also rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information. Our research collaborators and scientific advisors may have rights to publish data and information in which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborators and advisors, our ability to receive patent protection or protect our proprietary information may be imperiled.

Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

The biotechnology industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Because patent applications are maintained in secrecy until the application is published, we may be unaware of third party patents that may be infringed by commercialization of EVK-001. In addition, identification of third party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could likely:

result in costly litigation;

divert the time and attention of our technical personnel and management;

cause development delays;

prevent us from commercializing EVK-001 until the asserted patent expires or is held finally invalid or not infringed in a court of law;

require us to develop non-infringing technology; or

require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent EVK-001 from being marketed. Any patent-related legal action against us claiming damages or seeking to enjoin commercial activities relating to our product candidate or processes could subject us to potential liability for damages and could require us to obtain a license to continue to manufacture or market EVK-001, or, if no such license were available on commercially viable terms, could require us to cease manufacturing and marketing of EVK-001. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidate or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing EVK-001, which could harm our business, financial condition and operating results. Whatever the outcome, any patent litigation would be costly and time consuming, could be distracting to our management, and could have a material adverse effect on our business.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ and consult with individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or consultants are subject to a continuing obligation to their former employers or clients (such as non-competition or non-solicitation

obligations) or claims that our employees, our consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or clients. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Financial Position and Need for Capital

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.*

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2012 with respect to this uncertainty. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted our resources to developing our product candidate, but it cannot be marketed until regulatory approvals have been obtained. Based upon our currently expected level of operating expenditures following the completion of our initial public offering, we expect to be able to fund our operations for approximately the next 18 months. This period could be shortened if there are any significant increases in planned spending on our EVK-001 development program or more rapid progress of our planned Phase 3 clinical trial than anticipated. There is no assurance that other financing will be

available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

We have incurred significant operating losses since inception, and we expect to incur losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.*

We have incurred significant operating losses since we were founded in 2007 and expect to incur significant losses for the next several years as we begin our Phase 3 clinical trial for EVK-001. Our net loss for the year ended December 31, 2012 and the nine months ended September 30, 2013 was $2.0 million and $1.2 million, respectively. As of December 31, 2012 and September 30, 2013, we had an accumulated deficit of $19.9 million and $21.1 million, respectively. Losses have resulted principally from costs incurred in our clinical trials, research and development programs and from our general and administrative expenses. In the future, we intend to continue to conduct research and development, clinical testing, regulatory compliance activities and, if EVK-001 is approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in our incurring further significant losses for the next several years.

We currently generate no revenue from sales, and we may never be able to commercialize EVK-001 or other marketable drugs. As a result, there can be no assurance that we will ever generate revenues or achieve profitability, which could impair our ability to sustain operations or obtain any required additional funding. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize EVK-001.*

We will require substantial future capital in order to complete the remaining clinical development for EVK-001 and to potentially commercialize this product candidate. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the initiation, progress, costs, results of and timing of our clinical development program for EVK-001, including our planned Phase 3 clinical trial;
- the need for, and the progress, costs and results of, any additional clinical trials of EVK-001 we may initiate based on the results of our planned clinical trials or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of EVK-001;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from the FDA, and any similar regulatory agencies;
- the timing and costs associated with manufacturing EVK-001 for clinical trials and other studies and, if approved, for commercial sale;
- our need and ability to hire additional management, development and scientific personnel;

- the cost to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

- the timing and costs associated with establishing sales and marketing capabilities;

- market acceptance of EVK-001;

- the extent to which we are required to pay milestone or other payments under our Questcor asset purchase agreement and the timing of such payments;

- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and

- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

Some of these factors are outside of our control. We cannot provide any assurance that our existing capital resources, which include the proceeds from our initial public offering, will be sufficient to enable us to fund the completion of our Phase 3 clinical trial and remaining development program, and, in any event, we will need to raise additional capital to submit marketing applications for and prepare for commercialization of EVK-001 should we receive product approval. We may need to raise additional funds in the near future to complete development activities for EVK-001.

We may seek additional funding through collaboration agreements and public or private financings. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, if required, we will be unable to complete the planned Phase 3 clinical trial for EVK-001 and may be required to significantly curtail all of our activities. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to our product candidate or some of our technologies or otherwise agree to terms unfavorable to us.

The terms of our secured debt facility require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.*

We have a $3.0 million loan and security agreement with Silicon Valley Bank that is secured by a lien covering substantially all of our assets, excluding intellectual property. As of September 30, 2013, the outstanding principal balance of the Silicon Valley Bank loan was $3.0 million. The loan agreement contains customary affirmative and negative covenants and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on transferring collateral, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments and creating other liens on our assets, in each case subject to customary exceptions. If we default under the loan agreement, the lender may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender s right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the loan agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of the transactions completed in connection with our initial public offering.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our initial public offering, our most recent private placement and other transactions that have occurred over the past three years, we may have experienced an ownership change. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2012, we had federal and state net operating loss carryforwards of approximately $18.6 million and $18.2 million, respectively, and federal research and development credits of $0.5 million which could be limited if we experience an ownership change.

Risks Related to Ownership of Our Common Stock

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

Prior to our initial public offering, there was no public market for our common stock, and an active trading market may never develop or be sustained. If an active trading market does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at a price that is attractive to you or at all. In addition, an inactive market may impair our ability to raise capital by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration, which, in turn, could materially adversely affect our business. Since the commencement of trading in connection with our initial public offering in September 2013 through November 8, 2013, the sale price per share of our common stock on The NASDAQ Capital Market has ranged from a low of $8.90 to a high of $14.25.

The price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.*

Our stock price is likely to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they purchased the shares. The market price for our common stock may be influenced by many factors, including:

- our ability to enroll patients in our planned Phase 3 clinical trial;
- results of the clinical trial, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory developments in the United States and foreign countries;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts reports or recommendations;
- sales of our stock by insiders and 5% stockholders;
- trading volume of our common stock;
- general economic, industry and market conditions other events or factors, many of which are beyond our control;
- additions or departures of key personnel; and

intellectual property, product liability or other litigation against us.

In addition, in the past, stockholders have initiated class action lawsuits against biotechnology and pharmaceutical companies following periods of volatility in the market prices of these companies stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management s attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our EVK-001 development program;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting EVK-001; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

We may allocate the net proceeds from our initial public offering in ways that our stockholders may not approve.

Our management has broad discretion in the application of the net proceeds from our initial public offering. Because of the number and variability of factors that will determine our use of the net proceeds from our initial

public offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of our common stock. We expect to use the net proceeds from our initial public offering for research and development activities for EVK-001, including our planned Phase 3 clinical trial of EVK-001, and for working capital and other general corporate purposes. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from our initial public offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from our initial public offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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

As of October 31, 2013, our executive officers, directors and greater than 5% stockholders, in the aggregate, owned approximately 56.2% of our outstanding common stock. As a result, such persons, acting together, will have the ability to control our management and affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. These persons will also have the ability to control our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our 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 staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- permitting our board of directors to accelerate the vesting of outstanding option grants upon certain transactions that result in a change of control; and

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

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We do not intend to pay dividends on our common stock and, consequently, the ability of our stockholders to achieve a return on their investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. 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. In addition, our loan and security agreement with Silicon Valley Bank currently prohibits us from paying dividends on our equity securities, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will

therefore be limited to the appreciation of their stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

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

Sales of a substantial number of shares of our common stock in the public market after the lock-up agreements and other legal restrictions on resale discussed in the final prospectus for our initial public offering lapse, or the perception that these sales might occur, could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

Based on shares of common stock outstanding as of October 31, 2013, we had outstanding a total of 6,096,752 shares of common stock. Of these shares, only the 2,415,000 shares of common stock sold by us in our initial public offering are freely tradable without restriction in the public market. However, Aegis Capital Corp. the representative of the underwriters for our initial public offering, may, in its sole discretion, permit our officers, directors and other stockholders who are subject to lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

We expect that the lock-up agreements pertaining to our initial public offering will expire 180 days after September 24, 2013, the date of the underwriting agreement pertaining to our initial public offering. After the lock-up agreements expire, up to an additional 3,681,752 shares of common stock will be eligible for sale in the public market, of which 3,427,622 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

As of October 31, 2013, the holders of 2,984,752 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. In addition, holders of 84,000 shares of common stock issuable upon the exercise of warrants will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following 2013, the year in which we completed our initial

public offering, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. 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 not being required to comply 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 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.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

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

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC, and The NASDAQ Stock Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. 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 such as say on pay and proxy access. Recent legislation permits smaller emerging growth companies to implement many of these requirements over a longer period and up to five years following their initial public offering. We are taking advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. 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 the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our consolidated net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. 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 the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If securities or industry analysts publish unfavorable research or reports 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, our business, our market or our competitors. We currently have limited research coverage by securities and industry analysts. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

We could be subject to 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 pharmaceutical 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.

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

From July 1, 2013 through September 30, we issued and sold the equity securities described below.

On September 24, 2013, our registration statement on Form S-1/A (File No. 333-188838), which registered an aggregate amount of up to $33.8 million of our common stock, was declared effective by the SEC for our initial public offering. At the closing of the offering on September 30, 2013, we sold 2,100,000 shares of common stock at an initial public offering price of $12.00 per share and received gross proceeds of $25.2 million, which resulted in net proceeds to us of approximately $21.7 million, after underwriting discounts, commissions and non-accountable expense allowance of approximately $2.1 million and offering-related transaction costs of approximately $1.4 million. Aegis Capital Corporation acted as the sole book-running manager and Cantor Fitzgerald & Company and Feltl and Company acted as co-managers for the offering.

On October 8, 2013, the underwriters exercised their over-allotment option to purchase an additional 315,000 shares of common stock at $12.00 per share. The over-allotment exercise is expected to result in estimated net proceeds to the Company of $3,440,000, after deducting $264,600 of underwriting discounts and commissions and an estimated $75,000 of additional IPO related costs.

Use of Proceeds.

We intend to use $15.0 million of the net proceeds of this offering for research and development activities for EVK-001, including our planned Phase 3 clinical trial of EVK-001. In addition, we intend to use $2.1 million of the net proceeds from this offering to make monthly principal and interest payments on our loan with Silicon Valley Bank. Advances under the loan and security agreement have an interest-only period through December 31, 2013, and a 24-month payback period commences in January 2014. We intend to use the remaining proceeds from this offering for working capital and other general corporate purposes. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products; however, we have no current commitments or obligations to do so. Pending use of the proceeds as described above, we intend to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade securities or certificates of deposit.

We believe that the net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations for approximately the next 18 months, although there can be no assurance in that regard. In particular, we believe that the net proceeds from this offering will allow us to commence our planned Phase 3 clinical trial of EVK-001. Because we expect this clinical trial to commence in the first half of 2014 with an approximately 12 month enrollment period, we may need to obtain additional funds to complete this trial as well as finance any additional development requirements requested by the FDA.

The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our clinical trials and other development efforts for EVK-001, as well as the amount of cash used in our operations. We therefore cannot estimate the amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

A list of exhibits is set forth on the Exhibit Index immediately following the signature page of this Quarterly Report on Form 10-Q, and is incorporated herein by reference.

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.

Evoke Pharma, Inc.

Date: November 13, 2013

By: /s/ David A. Gonyer
David A. Gonyer

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 13, 2013

By: /s/ Matthew J. D Onofrio
Matthew J. D Onofrio

Executive Vice President, Chief Business Officer, Treasurer and Secretary

(Principal Financial and Accounting Officer)

Index to Exhibits

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation
3.2(1)	Amended and Restated Bylaws
4.1(2)	Specimen Common Stock Certificate
4.2(3)	Investor Rights Agreement dated as of June 1, 2007
4.3(3)	Warrant dated February 7, 2007 issued by the Registrant to Square 1 Bank
4.4(3)	Warrant dated June 1, 2012 issued by the Registrant to Silicon Valley Bank
4.5(2)	Form of Warrant Agreement issued by the Registrant to the representative of the underwriters and certain of its affiliates in connection with the closing of the Registrant s initial public offering
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15-d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15-d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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

(1) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed with the SEC on September 30, 2013.

(2) Incorporated by reference to Amendment No. 3 to the Registrant s Registration Statement on Form S-1 (Registration No. 333-188838), filed with the SEC on August 16, 2013.

(3) Incorporated by reference to the Registrant s Registration Statement on Form S-1 (Registration No. 333-188838), filed with the SEC on May 24, 2013.

* These certifications are being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

** Users of this data are advised that pursuant to Rule 406T of Regulation S-T, this XBRL information is being furnished and not filed herewith for purposes of Section 18 of the Securities Exchange Act of 1934, as amended,

and Sections 11 or 12 of the Securities Act of 1933, as amended, and is not to be incorporated by reference into any filing, or part of any registration statement or prospectus, of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.