Evoke Pharma Inc
Form 10-Q
November 13, 2014

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, 2014

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.)
505 Lomas Santa Fe Drive, Suite 270, Solana Beach, CA	92075
(Address of principal executive offices)	(Zip Code)

Registrant’s telephone number, including area code: (858) 345-1494

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§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, 2014, the registrant had 6,112,091 shares of Common Stock outstanding.

Evoke pharma, inc.

Form 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Evoke Pharma, Inc.

Condensed Balance Sheets

	September 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current Assets:		
Cash and cash equivalents	$12,176,682	$24,196,691
Prepaid expenses	1,131,685	234,262
Total current assets	13,308,367	24,430,953
Other assets	82,553	555,505
Total assets	$13,390,920	$24,986,458
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	$1,049,369	$284,915
Accrued compensation	636,098	557,399
Current portion of long-term debt	—	1,442,592
Total current liabilities	1,685,467	2,284,906
Deferred rent expense	14,714	6,830
Long-term debt, net of current portion	—	1,511,461
Total liabilities	1,700,181	3,803,197
Stockholders' equity:		
Common stock, $0.0001 par value; authorized shares — 50,000,000; issued and outstanding shares — 6,112,091 at September 30, 2014 and 6,096,752 at December 31, 2013	611	610
Additional paid-in capital	44,709,474	43,874,119

Accumulated deficit	(33,019,346)	(22,691,468)
Total stockholders' equity	11,690,739	21,183,261
Total liabilities and stockholders' equity	$13,390,920	$24,986,458

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	$3,088,373	$78,731	$7,815,466	$320,558
General and administrative	732,800	406,862	2,420,167	700,489
Total operating expenses	3,821,173	485,593	10,235,633	1,021,047
Loss from operations	(3,821,173)	(485,593)	(10,235,633)	(1,021,047)
Other income (expense):				
Interest income	1,725	629	8,995	2,850
Interest expense	(5,906)	(39,940)	(101,240)	(119,570)
Change in fair value of warrant liability	—	39,000	—	(82,000)
Total other income (expense)	(4,181)	(311)	(92,245)	(198,720)
Net loss and comprehensive loss	$(3,825,354)	$(485,904)	$(10,327,878)	$(1,219,767)
Net loss per common share, basic and diluted	$(0.63)	$(0.41)	$(1.71)	$(1.06)
Weighted-average shares used to compute basic and diluted net loss per share	6,054,250	1,190,212	6,028,309	1,153,751

See accompanying notes to these unaudited condensed financial statements.

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Evoke Pharma, Inc.

Condensed Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,	
	2014	2013
Operating activities		
Net loss	$(10,327,878)	$(1,219,767)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	792,481	13,881
Non-cash interest	54,076	17,446
Change in fair value of warrant liability	—	82,000
Deferred rent expense	7,884	—
Changes in operating assets and liabilities:		
Prepaid expenses	(349,915)	—
Accounts payable and accrued expenses	843,153	(44,562)
Net cash used in operating activities	(8,980,199)	(1,151,002)
Financing activities		
Proceeds from bank line of credit and loan advances	—	2,000,000
Payments on bank line of credit	(3,000,000)	—
Costs paid in connection with loan origination	(82,685)	
Proceeds from issuance of common stock	42,875	25,200,000
Costs paid in connection with initial public offering	—	(2,426,958)
Net cash provided by (used in) financing activities	(3,039,810)	24,773,042
Net increase (decrease) in cash and cash equivalents	(12,020,009)	23,622,040
Cash and cash equivalents at beginning of the period	24,196,691	116,013
Cash and cash equivalents at end of the period	$12,176,682	$23,738,053
Supplemental disclosures of cash flow information		
Interest paid	$58,790	$94,750
Supplemental disclosures of non-cash financing information		
Issuance of Series A Convertible Preferred Stock warrants	—	$49,000

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

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 publicly-held specialty pharmaceutical company focused primarily on the development of drugs to treat gastroenterological disorders and disease.

Since its inception, 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. The Company does not anticipate realizing revenues for the foreseeable future. The Company's activities are subject to significant risks and uncertainties, including funding its operations beyond the completion of its ongoing Phase 3 clinical trial for EVK-001.

In the quarter ended June 30, 2014, the Company early adopted ASU No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. Please refer to Note 2 for further details.

2. Summary of Significant Accounting Policies

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 the 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, 2013, which is contained in the Company's Annual Report on Form 10-K filed with the SEC on March 25, 2014. 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 at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Stock-Based Compensation

Stock-based compensation expense for stock option grants and employee stock purchase plan shares is recorded at the estimated fair value of the award as of the grant date and is recognized as expense on a straight-line basis over the

requisite service period of the stock-based award. The estimation of stock option and employee stock purchase plan fair value requires management to make estimates and judgments about, among other things, employee exercise behavior, forfeiture rates and volatility of the Company's common stock. The judgments directly affect the amount of compensation expense that will be recognized.

Research and Development Expenses

Research and development costs are expensed as incurred and primarily include compensation and related benefits, stock-based compensation expense, and costs paid to third-party contractors to perform research, conduct clinical trials and develop drug materials and delivery devices. The Company expenses costs relating to the purchase and production of pre-approval product inventories as research and development expense in the period incurred until U.S. Food and Drug Administration ("FDA") approval is received.

The Company bases its expense accruals related to clinical studies on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical studies on its behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients, site initiation and the completion of clinical study milestones. Service providers typically invoice the Company monthly in arrears for services performed. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the Company does not identify costs that have begun to be incurred, or if the Company underestimates or overestimates the level of services performed or the costs of these services, actual expenses could differ from estimates. To date, the Company has not experienced significant changes in estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, no assurance can be made that changes to the estimates will not be made in the future as the Company becomes aware of additional information about the status or conduct of clinical studies and other research activities.

The Company does not own or operate manufacturing facilities for the production of EVK-001, nor does it plan to develop its own manufacturing operations in the foreseeable future. The Company currently depends on third-party contract manufacturers for all of its required raw materials, drug substance and finished product for its pre-clinical research and clinical trials. The Company does not have any current contractual relationships for the manufacture of commercial supplies of EVK-001. If EVK-001 is approved by any regulatory agency, the Company intends to enter into agreements with third-party contract manufacturers for the commercial production at that time. The Company currently utilizes a third-party consultant, which it engages on an as-needed, hourly basis, to manage its manufacturing contractors.

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 49,375, 71,875, 101,875, and 105,625 weighted-average shares subject to repurchase from the weighted-average number of common shares outstanding for the three and nine months ended September 30, 2014 and 2013, 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 warrants for the purchase of common stock, options outstanding under the Company's equity incentive plans and potential shares to be purchased under the Company's employee stock purchase plan. For the 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 sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive:

	Three and Nine Months Ended September 30,	
	2014	2013
Warrants to purchase common stock	96,000	106,000
Common stock options	683,500	231,250
Employee stock purchase plan	3,161	—
	782,661	337,250

Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board ("FASB"), issued an Accounting Standards Update No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. This guidance removes the definition of a development stage entity from FASB's accounting standards codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the guidance eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The guidance becomes effective in the first annual period beginning after December 15, 2014, with an option for early adoption. The Company chose to early adopt this standard during the quarter ended June 30, 2014.

In August 2014, the FASB issued an amendment to the accounting guidance related to the evaluation of an entity to continue as a going concern. The amendment establishes management's responsibility to evaluate whether there is

substantial doubt about an entity's ability to continue as a going concern in connection with preparing financial statements for each annual and interim reporting period. The amendment also gives guidance to determine whether to disclose information about relevant conditions and events when there is substantial doubt about an entity's ability to continue as a going concern. The amended guidance is effective prospectively for fiscal years beginning after December 15, 2016. The new guidance will not have an impact on the Company's financial position, results of operations or cash flows.

3. Debt

In June 2012, the Company entered into a $3 million loan and security agreement with Silicon Valley Bank ("SVB"), collateralized by the Company's personal property. The agreement also contained non-financial covenants. By January 2013, the Company had been advanced the entire $3 million. Interest on advances under the agreement was at a fixed interest rate equal to 4.50%. Advances under the loan and security agreement had an interest-only period through December 31, 2013, and had a 24-month payback period that commenced in January 2014. On May 23, 2014, the Company repaid the outstanding principal and accrued interest of approximately $2.4 million to SVB. With such payoff, the SVB loan agreement and the documents entered into in connection therewith were deemed to be terminated. SVB's security interest in substantially all of the Company's assets was also terminated.

On May 28, 2014 (the "closing date"), the Company entered into a loan and security agreement (the "credit facility") with Square 1 Bank ("Square 1"), pursuant to which Square 1 agreed to make term loans available to the Company for general corporate and working capital purposes and for capital expenditures, in a principal amount of up to $4.5 million. The Company did not draw from the credit facility on the closing date, and has not drawn any funds as of the date of this report. The term loans will be funded at the Company's request prior to November 28, 2015, subject to customary conditions for funding including, among others, that no event of default exists. The Company may not request more than four term loans during the term of the credit facility. The credit facility is secured by substantially all of the Company's personal property other than its intellectual property.

Each term loan under the credit facility bears interest at either (A) a variable annual rate equal to the greater of (1) 1.75% above Square 1's most recently announced prime rate, or (2) 5.00%, or (B) a fixed annual rate of 5.50%, such rate to be fixed at the time of the initial borrowing at the Company's election and shall be applicable to all term loans funded under the credit facility. The Company is required to make interest-only payments through November 28, 2015 on any term loans that it draws. All outstanding term loans under the credit facility will begin amortizing at the end of the interest-only period, with monthly payments of principal and interest being made by the Company to Square 1 in consecutive monthly installments following November 28, 2015. All term loans under the credit facility mature on November 28, 2017. At the Company's option, it may prepay the outstanding principal balance of the term loans before November 28, 2017 without penalty or premium.

The credit facility includes affirmative and negative covenants applicable to the Company and any subsidiaries it creates in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and meet certain covenants with respect to enrollment and results of its EVK-001 Phase 3 trial (METO-IN-003). After the Company receives positive results from the Phase 3 trial, if at all (which the Company must achieve on or prior to September 30, 2015), it must either maintain a ratio of its cash at Square 1 to its cash burn over the preceding month of at least 3.00 to 1.00, or it must deliver evidence of a forthcoming financing or strategic partnership arrangement to Square 1, in each case in an amount satisfactory to Square 1. The negative covenants include, among others, restrictions on the Company's transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens and selling assets, in each case subject to certain exceptions.

The credit facility also includes events of default, the occurrence and continuation of which provide Square 1 with the right to exercise remedies against the Company and the collateral securing the term loans under the credit facility, including foreclosure against the Company's properties securing the credit facilities, including its cash. These events of default include, among other things, the Company's failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $400,000 and a final judgment against the Company in an amount greater than $400,000.

In connection with each funding of the term loans, the Company will issue to Square 1 a warrant to purchase up to the number of shares of the Company's common stock equal to (A) 3% of the principal amount of the applicable term loan credit extension over (B) the initial exercise price, which shall be the closing price of the common stock on the day of such funding. The warrants will expire ten years from each date of issuance. If a warrant has not been exercised prior to its expiration date, it will be deemed to automatically convert by "cashless" conversion. In the event that the Company is acquired, the warrants will be exercisable or deemed automatically converted, which shall be determined based upon whether the Company's successor assumes the obligations of the warrant.

The Company incurred approximately $83,000 of loan origination costs related to this credit facility. Such costs have been capitalized and are being amortized over the 42 month term of the credit facility.

4. Acquisition of Technology

In June 2007, the Company purchased from Questcor Pharmaceuticals, Inc. ("Questcor") all rights and patents to a development program for the Company's EVK-001 product candidate for an upfront payment of $650,000, which was expensed as in-process research and development. In May 2014, the Company paid a milestone payment of $500,000 to Questcor based upon the initiation of the first patient dosing in its Phase 3 clinical trial for EVK-001. In August 2014, Mallinckrodt plc, or Mallinckrodt, acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the Asset Purchase Agreement with the Company to Mallinckrodt. In addition to the payments

made to Questcor, the Company may be required to make additional milestone payments to Mallinckrodt totaling up to $51.5 million. These milestones include up to $4.5 million in payments if EVK-001 achieves the following development targets:

$1.5 million upon the FDA's acceptance for review of a new drug application for EVK-001; and
$3 million upon the FDA's approval of EVK-001.

The remaining $47 million in milestone payments depend on EVK-001's commercial success and will only apply if EVK-001 receives regulatory approval. In addition, the Company will be required to pay Mallinckrodt a low single digit royalty on net sales of EVK-001. The Company's 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.

5. Stockholders' Equity

Stock-Based Compensation

Stock-based compensation expense includes charges related to stock option grants and employee stock purchases under the Company's employee stock purchase plan. The Company measures stock-based compensation expense based on the grant-date fair value of any awards granted to its employees. Such expense is recognized over the period of time that employees provide service and earn rights to the awards.

The estimated fair value of each stock option award granted was determined on the date of grant using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for option grants during the three and nine months ended September 30, 2014.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Common Stock Options				
Risk free interest rate	—	1.75%	1.66-1.77%	1.75%
Expected option term	—	6 years	5.5-6.0 years	6 years
Expected volatility of common stock	—	70.8%	71.06-73.21%	70.8%
Expected dividend yield	—	0.00%	0.00%	0.00%

The estimated fair value of each employee stock purchase plan award was determined on the date of grant using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for the employee stock purchase plan during the three and nine months ended September 30, 2014. The employee stock purchase plan did not become active until March 2014.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Employee Stock Purchase Plan				
Risk free interest rate	0.05%	—	0.05-0.08%	—
Expected option term	6 months	—	6 months	—
Expected volatility of common stock	69.32%	—	69.32-73.21%	—
Expected dividend yield	0.00%	—	0.00%	—

The risk-free interest rate assumption was based on the yield of an applicable rate for U.S. Treasury instruments with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company never paying cash dividends and having no expectation of paying cash dividends in the foreseeable future. The weighted average expected term of options and employee stock purchases was calculated using the simplified method as prescribed by accounting guidance for stock-based compensation. This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility was calculated based upon the Company's historical volatility, supplemented with historical volatility of comparable companies in the biotechnology industry whose share prices are publicly available for a sufficient period of time.

The Company recognized non-cash stock-based compensation expense to employees and directors in its research and development and its general and administrative functions as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	$105,145	$313	302,569	$4,377
General and administrative	198,816	7,316	489,912	9,504
Total stock-based compensation expense	$303,961	$7,629	792,481	$13,881

As of September 30, 2014, there was approximately $2.6 million of unrecognized compensation costs related to outstanding employee and board of director options, which is expected to be recognized over a weighted average period of 1.4 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, 2013 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 25, 2014. Past operating results are not necessarily indicative of results that may occur in future periods.

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 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," "intend," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other 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. Given these risks, uncertainties and other factors, 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. You should read this Quarterly Report on Form 10-Q completely. 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. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Evoke," "we," "us" and "our" refer to Evoke Pharma, Inc.

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. In April 2014, we commenced a Phase 3 clinical trial of EVK-001 in female patients with symptoms associated with acute and recurrent diabetic gastroparesis. This Phase 3 clinical trial is

a multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluating the efficacy, safety and population pharmacokinetics of EVK-001 in adult female subjects with diabetic gastroparesis when dosed four times a day for 28 days. The Phase 3 trial is expected to enroll 200 patients at sites across the United States. We will need to successfully complete this trial, as well as a thorough ECG (QT) study, which is an evaluation of cardiac safety, before we are able to submit a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for EVK-001. We commenced the thorough ECG (QT) study in August 2014 and completed enrollment in September 2014. We expect to provide top-line data from the ECG (QT) study by the end of 2014.

We are also conducting a companion clinical trial with EVK-001 in male patients with symptoms associated with acute and recurrent diabetic gastroparesis to assess the safety and efficacy of EVK-001 in men. The male companion trial was initiated in May 2014 and is designed similarly to the Phase 3 trial in women. This trial was requested by the FDA, but is not required for submission of the EVK-001 NDA for women; however, we expect to include safety data from this trial in the NDA submission.

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 convertible preferred stock, borrowings under loan and security agreements and the sale of shares in our initial public offering, or IPO, in September 2013. 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. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

Questcor Asset Purchase Agreement

We acquired all worldwide rights, data, patents and other related assets associated with EVK-001 from Questcor Pharmaceuticals, Inc., or Questcor, in June 2007. We paid to Questcor $650,000 in the form of an upfront payment and paid a milestone payment of $500,000 in May 2014 based upon the initiation of the first patient dosing in our Phase 3 clinical trial for EVK-001. In August 2014, Mallinckrodt plc, or Mallinckrodt, acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the Asset Purchase Agreement with the Company to Mallinckrodt. In addition to the payments we made to Questcor, we may also be required to make additional milestone payments to Mallinckrodt totaling up to $51.5 million. These milestones include up to $4.5 million in payments if EVK-001 achieves the following development targets:

·$1.5 million upon the FDA's acceptance for review of an NDA for EVK-001; and
·$3 million upon the FDA's approval of EVK-001.

The remaining $47 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 Mallinckrodt 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.

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 CRO, 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 ongoing Phase 3 clinical trial. 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 estimated that the costs to complete our Phase 3 clinical trial in women, our companion clinical trial in men and a thorough ECG (QT) study of EVK-001 will be approximately $15 million, of which, through September 30, 2014, $6.1 million have been incurred related to those clinical activities. 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. Other general and administrative expenses include professional fees for accounting, tax, patent costs, legal services, insurance, facility costs and costs associated with being a publicly-traded company. 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 SEC

requirements. These increases will likely include 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 on our outstanding debt and changes in the fair value of our warrant 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, or 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 consolidated financial statements, as well as the reported revenues and 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.

There were no significant changes during the nine months ended September 30, 2014 to the critical accounting policies described in "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

Other Information

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more, (b) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO, (c) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

Results of Operations

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

The following table summarizes the results of our operations for the three months ended September 30, 2014 and 2013:

	Three Months Ended September 30,		Increase/ (Decrease)
	2014	2013	
Research and development expenses	$3,088,373	$78,731	$3,009,642
General and administrative expenses	$732,800	$406,862	$325,938
Other expense	$4,181	$311	$3,870

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2014 compared to the three months ended September 30, 2013 increased by approximately $3,010,000 primarily due to research and development activities expanding subsequent to our IPO in September 2013. Costs incurred in 2014 include approximately $2,583,000 related to our ongoing clinical trials for EVK-001, $56,000 related to stability testing and preparation for the production of additional EVK-001 and approximately $441,000 for wages, taxes and employee insurance, including $105,000 of stock-based compensation expense, as we added clinical personnel subsequent to our IPO and the allocation of time spent by our executive team to research and development activities in 2014 increased compared to the time allocated in 2013 when they were primarily preparing for our IPO.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2014 compared to the three months ended September 30, 2013 increased by approximately $326,000 primarily due to general and administrative activities expanding subsequent to our IPO. Costs incurred in 2014 primarily included approximately $392,000 for wages, taxes and employee insurance, including $199,000 of stock-based compensation expense, as we added general and administrative personnel subsequent to our IPO, and approximately $277,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

Other Expense. Other expense for the three months ended September 30, 2014 primarily related to net interest expense incurred associated with the amortization of issuance costs for the Square 1 Bank loan. Other expense for the three months ended September 30, 2013 primarily consisted of net interest expense related to our Silicon Valley Bank loan and to the decrease in the fair value of our outstanding warrant liability in effect prior to our IPO.

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

The following table summarizes the results of our operations for the nine months ended September 30, 2014 and 2013:

	Nine Months Ended September 30,		Increase/ (Decrease)
	2014	2013	
Research and development expenses	$7,815,466	$320,558	$7,494,908
General and administrative expenses	$2,420,167	$700,489	$1,719,678
Other expense	$92,245	$198,720	$(106,475)

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 increased by approximately $7,495,000 primarily due to research and development activities expanding subsequent to our IPO. Costs incurred in 2014 include approximately $5,551,000 related to the ongoing clinical trials for EVK-001, $311,000 related to stability testing and preparation for the production of additional EVK-001, the payment of $500,000 to Questcor for achieving a milestone associated with the acquisition of our technology, and approximately $1,445,000 for wages, taxes and employee insurance, including $303,000 of stock-based compensation expense, as we added clinical personnel subsequent to our IPO and the allocation of time spent by our executive team to research and development activities in 2014 increased compared to the time allocated in 2013 when they were primarily preparing for our IPO. In addition, during the first quarter of 2013, the 2012 bonus accrual was reversed due to the election by our board of directors to not pay 2012 bonuses in order to conserve cash.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 increased by $1,720,000 primarily due to general and administrative activities expanding subsequent to our IPO. Costs incurred in 2014 primarily included approximately $1,097,000 for wages, taxes and employee insurance, including $490,000 of stock-based compensation expense, as we added general and administrative personnel subsequent to our IPO, and approximately $1,102,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. In addition, during the first quarter of 2013, the 2012 bonus accrual was reversed due to the election by our board of directors to not pay 2012 bonuses in order to conserve cash.

Other Expense. Other expense for the nine months ended September 30, 2014 primarily related to $46,000 of net interest expense incurred related to our bank loans and the write-off of approximately $46,000 of unamortized debt discount costs upon the repayment of the Silicon Valley Bank loan. Other expense for the nine months ended September 30, 2013 primarily consisted of approximately $117,000 of net interest expense related to advances under our bank loan and $82,000 of expenses related to the increase in the fair value of our outstanding warrant liability in effect prior to our IPO.

Liquidity and Capital Resources

Since our inception in 2007, we have funded our operations primarily from the sale of equity securities and borrowings under loan and security agreements. Prior to our IPO, we received $17.7 million in net proceeds from the sale of our Series A convertible preferred stock and advances of $5.5 million under the loan and security agreements. During 2013, we completed our IPO and raised approximately $25.1 million, net of offering costs and commissions. We have incurred losses since inception and have negative cash flows from operating activities. As of September 30, 2014, we had approximately $12.2 million in cash and cash equivalents, working capital of approximately $11.6 million and an accumulated deficit of approximately $33.0 million.

In June 2012, we entered into a $3 million loan and security agreement collateralized by our personal property and containing only non-financial covenants. By January 2013, we had been advanced the entire $3 million to fund working capital. Interest on advances under the agreement was at a fixed interest rate equal to 4.50%. Advances under the loan and security agreement had an interest-only period through December 31, 2013, and had a 24-month payback period that commenced in January 2014. In connection with the loan and security agreement, we issued a warrant to Silicon Valley Bank, or SVB, which is immediately exercisable for an aggregate of 12,000 shares of our common stock, at an exercise price of $7.50 per share. On May 23, 2014, we repaid the outstanding principal and accrued interest of approximately $2.4 million to SVB. With such payoff, the SVB loan agreement and the documents entered into in connection therewith were deemed to be terminated. SVB's security interest in substantially all of our assets was also terminated.

On May 28, 2014, or the closing date, we entered into a loan and security agreement, or credit facility, with Square 1 Bank, or Square 1, pursuant to which Square 1 agreed to make term loans available to us for general corporate and working capital purposes and for capital expenditures, in a principal amount of up to $4.5 million. We did not draw from the credit facility on the closing date, and have not drawn any funds as of the date of this report. The term loans will be funded at our request prior to November 28, 2015, subject to customary conditions for funding including, among others, that no event of default exists. We may not request more than four term loans during the term of the credit facility. The credit facility is secured by substantially all of our personal property other than our intellectual property.

Each term loan under the credit facility bears interest at either (A) a variable annual rate equal to the greater of (1) 1.75% above Square 1's most recently announced prime rate, or (2) 5.00%, or (B) a fixed annual rate of 5.50%, such rate to be fixed at the time of the initial borrowing at our election and shall be applicable to all term loans funded under the credit facility. We are required to make interest-only payments through November 28, 2015 on any term loans that we draw. All outstanding term loans under the credit facility will begin amortizing at the end of the interest-only period, with monthly payments of principal and interest being made by us to Square 1 in consecutive monthly installments following

November 28, 2015. All term loans under the credit facility mature on November 28, 2017. At our option, we may prepay the outstanding principal balance of the term loans before November 28, 2017 without penalty or premium.

The credit facility includes affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and meet certain covenants with respect to enrollment and results of our ongoing EVK-001 Phase 3 clinical trial. After we receive positive results from the Phase 3 trial, if at all (which we must achieve on or prior to September 30, 2015), we must either maintain a ratio of our cash at Square 1 to our cash burn over the preceding month of at least 3.00 to 1.00, or we must deliver evidence of a forthcoming financing or strategic partnership arrangement to Square 1, in each case in an amount satisfactory to Square 1. The negative covenants include, among others, restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens and selling assets, in each case subject to certain exceptions.

The credit facility also includes events of default, the occurrence and continuation of which provide Square 1 with the right to exercise remedies against us and the collateral securing the term loans under the credit facility, including foreclosure against our properties securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $400,000 and a final judgment against us in an amount greater than $400,000.

In connection with each funding of the term loans, we will issue to Square 1 a warrant to purchase up to the number of shares of our common stock equal to (A) 3% of the principal amount of the applicable term loan credit extension over (B) the initial exercise price, which shall be the closing price of our common stock on the day of such funding. The warrants will expire ten years from each date of issuance. If a warrant has not been exercised prior to its expiration date, it will deemed to automatically convert by “cashless” conversion. In the event that we are acquired, the warrants will be exercisable or deemed automatically converted, which shall be determined based upon whether our successor assumes the obligations of the warrant.

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:

- conduct significant clinical trials associated with EVK-001, including our ongoing Phase 3 clinical trial in women and the companion clinical trial in men that we commenced in April 2014, along with our thorough ECG (QT) trial which commenced in August 2014;
- maintain, expand and protect our intellectual property portfolio; and
- continue to fund the additional accounting, legal, insurance and other costs associated with being a public company

Although our current cash and cash equivalents are expected to be sufficient for us to complete our ongoing Phase 3 clinical trial of EVK-001 in women, the companion trial in men and the thorough ECG (QT) trial, it will not be sufficient to complete any additional development requirements requested by the FDA, or, if applicable, to 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 ECG (QT) study of EVK-001 will be approximately $15 million, of which, through September 30, 2014, $6.1 million have been incurred related to those clinical activities. Accordingly, we will continue to require substantial additional capital beyond our current cash and cash equivalents to continue our clinical development and 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 summarizes our cash flows for the nine months ended September 30, 2014 and 2013:

	Nine Months Ended September 30,	
	2014	2013
Net cash used in operating activities	$(8,980,199)	$(1,151,002)
Net cash provided by (used in) financing activities	$(3,039,810)	$24,773,042
Net increase (decrease) in cash and cash equivalent	$(12,020,009)	$23,622,040

Operating Activities. The primary use of our cash has been to fund our operations.

Financing Activities. During the nine months ended September 30, 2014, we repaid our outstanding loan balance of $3 million to SVB and paid approximately $83,000 for origination costs related to our loan and security agreement with Square 1. During the nine months ended September 30, 2013, our financing activity consisted of the receipt of a $2 million advance on our loan and security agreement with Silicon Valley Bank to fund

working capital requirements and the net proceeds of approximately $22.8 million from our IPO. Approximately $1.1 million of additional IPO costs incurred in the nine months ended September 30, 2013 were paid in October 2013.

We believe that our existing cash and cash equivalents as of September 30, 2014, together with interest thereon, will be sufficient to meet our anticipated cash requirements until mid-2015. 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 ongoing 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 ongoing 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 Mallinckrodt 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.

Off-Balance Sheet Arrangements

Through September 30, 2014, 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.

Contractual Obligations and Commitments

As of September 30, 2014, there have been no material changes, outside the ordinary course of our business, to the contractual obligations we described in “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations and Commitments” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

As of September 30, 2014, there have been no material changes in our market risk from that described in “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Quantitative and Qualitative

Disclosures about Market Risk" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

Item 4. Controls and Procedures

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines 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 only provide reasonable assurance of achieving the desired control objectives, and 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 required by SEC Rule 13a-15(b), 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 of the end of the period covered by this report. Based on the foregoing, 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, 2014.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are 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

There have been no material changes to the risk factors included in "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, other than those set forth below, which should be read in conjunction with the risk factors disclosed therein.

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, for which we initiated a Phase 3 clinical trial in April 2014. 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 ongoing Phase 3 clinical trial of EVK-001, which we commenced in April 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 ongoing clinical trials may not confirm the positive results of earlier clinical trials, particularly because we are utilizing a modified patient report outcomes instrument for our current 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 an 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. We believe, based on our current operating plan, that our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations until mid-2015, although there can be no assurance in that regard. Since our ongoing Phase 3 clinical trial of EVK-001, which commenced in April 2014, has 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;
- the 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 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, along with a thorough ECG (QT) trial, we believe will be sufficient for NDA submission seeking an indication of treatment of symptoms associated with diabetic gastroparesis in women. In April 2014, we commenced a multicenter, randomized, double-blind, placebo-controlled, parallel-group Phase 3 clinical trial to evaluate the efficacy, safety and population pharmacokinetics of EVK-001 in adult female subjects with diabetic gastroparesis when dosed four times a day for 28 days. Although we believe successful results from this single Phase 3 clinical trial, along with a thorough ECG (QT) 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 are conducting 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.

The terms of our secured credit 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 $4.5 million loan and security agreement with Square 1 that is secured by a lien covering substantially all of our personal property, excluding intellectual property. As of the date of this report, we have not drawn down on the credit facility. The credit facility contains affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and meet certain covenants with respect to enrollment and results of our Phase 3 trial for EVK-001. After we receive positive results from our Phase 3 trial, if at all (which we must achieve on or prior to September 30, 2015), we must either maintain a ratio of our cash at Square 1 to our cash burn over the preceding month of at least 3.00 to 1.00, or we must deliver evidence of a forthcoming financing or strategic partnership arrangement to Square 1, in each case in an amount satisfactory to Square 1. The negative covenants include, among others, restrictions on transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens and selling assets, in each case subject to certain exceptions. The credit facility also includes events of default, the occurrence and continuation of which provide Square 1 with the right to exercise remedies against us and the collateral securing the term loans under the credit facility, including foreclosure against our properties securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $400,000 and a final judgment against us in an amount greater than $400,000. Square 1 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.

Risks Related to Our Financial Position and Need for Capital

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 progress, costs, results of and timing of our clinical development program for EVK-001, including our ongoing 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 and ongoing 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 Mallinckrodt 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. For example, in November 2014 we entered into an At Market Issuance Sales Agreement, or the Sales Agreement, with MLV & Co. LLC, or MLV, pursuant to which we may sell from time to time, at our option, up to an aggregate of $6.6 million of shares of our common stock through MLV, as sales agent. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made on The Nasdaq Capital Market under our shelf registration statement on Form S-3 filed on November 13, 2014, following such time as the registration statement is declared effective by the SEC, by means of ordinary brokers' transactions at market prices. However, there can be no assurance that MLV will be successful in consummating such sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. Under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than $75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the Sales Agreement, will be limited to an aggregate of one-third of our public float. As of November 11, 2014, our public float was 2.9 million shares, the value of which was $20.0 million based upon the closing price of our common stock of $6.86 on such date. The value of one-third of our public float calculated on the same basis was $6.6 million. In addition, we will not be able to make sales of our common stock pursuant to the Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to MLV under the sales agreement. In addition, MLV is permitted to terminate the Sales Agreement in its sole discretion upon ten days' notice, or at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on our assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations.

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 and dilute the holdings of our existing stockholders.

If we are unable to obtain funding on a timely basis, if required, we will be unable to complete the ongoing 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.

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

From January 1, 2014 through September 30, 2014 we issued 2,795 shares of common stock as a result of a cashless exercise of a warrant, 5,250 shares of common stock through the exercise of a stock option and 7,294 shares of common stock through our employee stock purchase plan.

Use of Proceeds

On September 24, 2013, our registration statement on Form S-1 (File No. 333-188839), which registered an aggregate amount of up to approximately $29 million of our common stock, was declared effective by the SEC for our IPO pursuant to which we sold 2,415,000 shares of common stock at an IPO price of $12.00 per share, including the exercise of the underwriters' over-allotment option. As a result of the IPO, we received gross proceeds of approximately $29 million, which resulted in net proceeds to us of approximately $25.1 million, after underwriting discounts, commissions and expenses of approximately $2.4 million and $1.5 million of other offering expenses. None of the expenses associated with the IPO were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates.

Through September 30, 2014, approximately $3.2 million of the net proceeds has been used to make principal and interest payments on our loan with Silicon Valley Bank and $9.7 million for working capital. Pending use of the net proceeds, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities. There has been no material change in the planned use of proceeds from our IPO from that described in the final prospectus filed with the SEC pursuant to Rule 424(b) on September 25, 2013.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

We have filed a shelf registration statement on Form S-3 with the SEC, which has not yet been declared effective. Under the rules and regulations of the SEC, upon its effectiveness, we can use the shelf registration statement to obtain additional financings from time to time, subject to the SEC's rules and regulations relating to eligibility to use Form S-3. Under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than $75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements will be limited to an aggregate of one-third of our public float. As of November 11, 2014, our public float was 2.9 million shares, the value of which was $20.0 million based upon the closing price of our common stock of $6.86 on such date. The value of one-third of our public float calculated on the same basis was $6.6 million.

On November 13, 2014, we entered into the Sales Agreement MLV, pursuant to which we may sell from time to time, at our option, up to an aggregate of $6.6 million of shares of our common stock through MLV, as sales agent. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made on The Nasdaq Capital Market, or the Exchange, under our registration statement on Form S-3 filed on November 13, 2014 by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the Sales Agreement, we may also sell shares of our common stock through MLV, on the Exchange or otherwise, at negotiated prices or at prices related to the prevailing market price. Under the terms of the Sales Agreement, MLV may not engage in any proprietary trading or trading as principal for MLV's own account. MLV will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We cannot provide any assurances that we will issue any shares pursuant to the Sales Agreement. We will pay a commission rate equal to up to 3% of the gross sales price per share sold. We have also agreed to provide MLV with customary indemnification and contribution rights.

The Sales Agreement will automatically terminate upon the sale of an aggregate of $6.6 million of shares of our common stock pursuant to the Sales Agreement. In addition, the Sales Agreement may be terminated by us or MLV at any time upon ten days' notice to the other party, or by MLV at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on our assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations.

The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the Sales Agreement, a copy of which is filed as Exhibit 1.2 to our registration statement on Form S-3 filed on November 13, 2014 with the SEC and is incorporated herein by reference.

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, 2014	By:	/s/ David A. Gonyer David A. Gonyer President and Chief Executive Officer (Principal Executive Officer)
Date: November 13, 2014	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 Exhibit
3.1(1)	Amended and Restated Certificate of Incorporation of the Company
3.2(1)	Amended and Restated Bylaws of the Company
4.1(2)	Form of the Company's Common Stock Certificate
4.2(3)	Investor Rights Agreement dated as of June 1, 2007
4.3(3)	Warrant dated June 1, 2012 issued by the Company to Silicon Valley Bank
4.4(2)	Form of Warrant Agreement dated September 30, 2013 issued by the Company to the representative of the underwriters and certain of its affiliates in connection with the closing of the Company's initial public offering
4.5(4)	Form of Warrant Agreement to be issued to Square 1 Bank under the Loan and Security Agreement, dated as of May 28, 2014, by and between the Company and Square 1 Bank
10.1(5)	At Market Issuance Sales Agreement, dated as of November 13, 2014, by and between the Company and MLV & Co. LLC
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
	XBRL Taxonomy Extension Schema Document

101.SCH

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 Company's Current Report on Form 8-K filed with the SEC on September 30, 2013.
(2) Incorporated by reference to the Company's Amendment No. 3 to Registration Statement on Form S-1 filed with the SEC on August 16, 2013.
(3) Incorporated by reference to the Company's Registration Statement on Form S-1 filed with the SEC on May 24, 2013.
(4) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on May 28, 2014.
(5) Incorporated by reference to the Company's Registration Statement on Form S-3, filed with the SEC on November 13, 2014.
* These certifications are being furnished solely to accompany this annual 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 Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.