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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

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 ☒ 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 ☒ 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	☒

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

As of November 4, 2016, the registrant had 12,350,360 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, 2016 (Unaudited)	December 31, 2015
Assets		
Current Assets:		
Cash and cash equivalents	$ 10,379,882	$ 8,691,155
Prepaid expenses	425,246	833,276
Other current assets	7,997	—
Total current assets	10,813,125	9,524,431
Other assets	—	7,997
Total assets	$ 10,813,125	$ 9,532,428
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 498,134	$ 927,606
Accrued compensation	513,509	760,782
Current portion of long-term debt	—	146,052
Total current liabilities	1,011,643	1,834,440
Warrant liability	5,098,404	—
Long-term debt, net of current portion	—	4,233,059
Total liabilities	6,110,047	6,067,499
Stockholders' equity:		
Common stock, $0.0001 par value; authorized shares — 50,000,000; issued and outstanding shares - 12,350,360 and 7,201,774 at September 30, 2016 and December 31, 2015, respectively	1,235	720
Additional paid-in capital	61,983,643	51,524,821
Accumulated deficit	(57,281,800)	(48,060,612)
Total stockholders' equity	4,703,078	3,464,929
Total liabilities and stockholders' equity	$ 10,813,125	$ 9,532,428

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Operations

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Operating expenses:				
Research and development	$ 1,339,343	$ 1,837,743	$ 5,449,568	$ 6,445,842
General and administrative	830,092	819,703	2,770,500	2,821,382
Total operating expenses	2,169,435	2,657,446	8,220,068	9,267,224
Loss from operations	(2,169,435)	(2,657,446)	(8,220,068)	(9,267,224)
Other expenses				
Interest expense, net	(123,209)	(77,954)	(268,483)	(230,087)
Financing costs related to warrant liability	(533,692)	—	(533,692)	—
Change in fair value of warrant liability	(198,945)	—	(198,945)	—
Total other expenses	(855,846)	(77,954)	(1,001,120)	(230,087)
Net loss	$ (3,025,281)	$ (2,735,400)	$ (9,221,188)	$ (9,497,311)
Net loss per common share, basic and diluted	$ (0.29)	$ (0.42)	$ (1.11)	$ (1.51)
Weighted-average shares used to compute basic and diluted net loss per share	10,614,692	6,494,845	8,341,750	6,271,002

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,	
	2016	**2015**
Operating activities		
Net loss	$ (9,221,188)	$ (9,497,311)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,298,279	1,127,813
Non-cash interest	120,889	45,521
Deferred rent expense	—	(9,227)
Financing costs allocated to warrant liability	533,692	—
Change in fair value of warrant liability	198,945	—
Change in operating assets and liabilities:		
Prepaid expenses and other assets	408,030	(4,405)
Accounts payable and accrued expenses	(676,745)	294,244
Net cash used in operating activities	(7,338,098)	(8,043,365)
Financing activities		
Payment of bank loan	(4,500,000)	—
Proceeds from issuance of common stock, net	358,023	4,626,373
Proceeds from issuance of common stock and warrants, net	13,168,802	—
Net cash provided by financing activities	9,026,825	4,626,373
Net increase (decrease) in cash and cash equivalents	1,688,727	(3,416,992)
Cash and cash equivalents at beginning of period	8,691,155	14,155,809
Cash and cash equivalents at end of period	$ 10,379,882	$ 10,738,817
Supplemental disclosure of cash flow information		
Interest paid	$ 169,813	$ 167,750
Non-cash financing activities		
Deferred financing costs paid in prior year	—	$ 137,812
Fair value of warrants issued to placement agent	$ 369,863	—

See accompanying notes to these unaudited condensed financial statements.

1. Organization and Basis of Presentation

Evoke Pharma, Inc. (the "Company") was incorporated in the state of Delaware in January 2007. 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 the significant risks and uncertainties associated with any specialty pharmaceutical company that has substantial expenditures for research and development, including funding its operations.

The Company has incurred recurring losses and negative cash flows from operations since inception and expects to continue to incur net losses for at least the next several years. As of September 30, 2016, the Company had an accumulated deficit of approximately $57.3 million. The Company expects operating losses and negative cash flows to continue for the foreseeable future until such time, if ever, that it can generate significant revenues from the sale of Gimoti™ (formerly known as EVK-001).

Clinical Trial Results

On July 18, 2016, the Company announced topline results from its Phase 3 clinical trial that evaluated the efficacy and safety of Gimoti in women with symptoms associated with diabetic gastroparesis. In this study, Gimoti did not achieve its primary endpoint of symptom improvement at Week 4.

To confirm the results of the Phase 2b trial in male subjects, the U.S. Food and Drug Administration (the "FDA") agreed that the Company could conduct a separate companion trial in men. The FDA recommended that the trials be conducted in parallel and when the Phase 3 study in women was complete, the Company could conduct an interim analysis on the male trial to determine whether or not it would be futile to continue to full enrollment. The Company conducted a multicenter, randomized, double-blind, placebo-controlled, parallel-group clinical study designed to evaluate the efficacy and safety of Gimoti in men with symptoms associated with diabetic gastroparesis. During November 2016, the Company determined the trial showed futility so that, even if the trial had fully been enrolled, the results would not have differed. As the Company anticipated at the beginning of the trial, based on the prior Phase 2b data, the results showed no statistical significant efficacy in men and the safety profile for Gimoti was favorable compared to placebo with good tolerability.

Sales of Common Stock and Warrants

On July 25, 2016 and August 3, 2016, the Company completed registered direct offerings of an aggregate of 5,048,632 shares of common stock for gross proceeds of $14.5 million. Concurrently in private placements, for each share of common stock purchased by an investor, such investor received from the Company an unregistered warrant to purchase shares of common stock. See Note 5 for further description.

Repayment of Debt

On August 4, 2016, the Company repaid in full the entire $4.5 million of outstanding principal and interest under the Loan and Security Agreement, dated as of May 28, 2014, as amended (the "Loan Agreement"), between the Company, as borrower, and Square 1 Bank, a division of Pacific Western Bank ("Square 1"), as lender. In connection with such repayment, the Loan Agreement was terminated, and all security, liens or other encumbrances on assets of the Company were released. See Note 3 for further description.

In addition to the financings that occurred in July and August 2016, the Company may need to raise additional funds to conduct further analyses of the Phase 3 trial data of Gimoti and assess continued development opportunities for this product candidate, to prepare for a meeting with the FDA, for other working capital and general corporate purposes. The Company believes that its current cash and cash equivalents, including the proceeds from the financings that occurred in July and August 2016 and after repayment of the debt, will be sufficient to meet estimated working capital requirements and fund operations through at least June 30, 2017. There can be no assurance that additional financing will be available when needed or on acceptable terms. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, financial condition and future prospects.

Going Concern

In its report on the Company's financial statements for the year ended December 31, 2015, the Company's independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Though the Company was able to raise aggregate net proceeds of approximately $13.2 million through sales of its common stock and warrants to purchase its common stock in July 2016 and August 2016, as of the date of this filing the Company believes that there is substantial doubt about its ability to continue as a going concern within one year after the financial statements are issued. Should the Company's assessment of the Phase 3 clinical trial data and/or other development opportunities result in the Company's determination to continue the development of Gimoti, the Company anticipates that it will need to continue to complete equity or debt financings to meet future product development milestones.

2. Summary of Significant Accounting Policies

The accompanying condensed balance sheet as of December 31, 2015, which has been derived from audited financial statements, and the unaudited interim condensed financial statements, have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and follow 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 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 year ended December 31, 2015, which are contained in the Company's Annual Report on Form 10-K filed with the SEC on March 10, 2016. The results for interim periods are not necessarily indicative of the results expected for the full 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 materially from those estimates.

Stock-Based Compensation

Stock-based compensation expense for stock option grants and employee stock purchases under the Company's Employee Stock Purchase Plan (the "ESPP") 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 employee's requisite service period. The estimation of stock option and ESPP 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.

The Company grants stock options to purchase common stock to employees and members of the board of directors with exercise prices equal to the Company's closing market price on the date the stock options are granted. 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 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 assumed dividend yield was based on the Company never paying cash dividends and having no expectation of paying cash dividends in the foreseeable future.

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 inventories as research and development expense in the period incurred until 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 contract research organizations ("CROs") 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 materially 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.

Included in research and development expenses for the three and nine months ended September 30, 2015 were costs of $58,933 and $121,422, respectively, for clinical trial services incurred by a related party of one of the Company's officers. There were no related party costs incurred during the nine months ended September 30, 2016.

The Company does not own or operate manufacturing facilities for the production of Gimoti, 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 preclinical research and clinical trials. Other than an agreement with Cosma S.p.A. to supply metoclopramide for the manufacture of Gimoti, the Company does not have any other contractual relationships for the manufacture of commercial supplies of Gimoti. If Gimoti 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.

Warrant Accounting

The Company's warrants to purchase shares of its common stock, issued as a part of the at-the-market registered direct offerings in July and August 2016, are classified as warrant liability and recorded at fair value. These warrants contain a feature that could require the transfer of cash in the event a change of control occurs without the authorization of our Board of Directors, and therefore, are classified as a liability in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480. Each warrant is initially recorded at fair value on the date of grant using the Black Scholes pricing model. This warrant liability is subject to remeasurement at each balance sheet date and the Company recognizes any change in fair value in its statements of operations as a change in fair value of the warrant liability. The Company will continue to adjust the carrying value of the warrants for changes in the estimated fair value until the earlier of the exercise or expiration of the warrants. At that time, the liabilities will be reclassified to additional paid-in capital, a component of stockholders' equity.

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 45,000 shares subject to repurchase from the weighted-average number of common shares outstanding for each of the three and nine months ended September 30, 2016 and 2015. 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 ESPP. 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 from the calculation of diluted net loss per share because to do so would be anti-dilutive:

	Three and Nine Months Ended September 30,	
	2016	**2015**
Common stock subject to repurchase	45,000	45,000
Warrants to purchase common stock	3,323,876	118,881
Common stock options	1,275,624	1,037,500
Employee stock purchase plan	10,938	5,706
Total excluded securities	4,655,438	1,207,087

Recent Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update ("ASU") 2014-15 (Subtopic 205-40), *Presentation of Financial Statements - Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* The guidance requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable). Management will be required to make this evaluation for both annual and interim reporting periods and will have to make certain disclosures if it concludes that substantial doubt exists or when its plans alleviate substantial doubt about the entity's ability to continue as a going concern. Substantial doubt exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). The term probable is used consistently with its use in ASC Topic 450, *Contingencies.* The guidance is effective for annual periods ending after December 15, 2016 and for interim reporting periods starting in the first quarter 2017, with early adoption permitted. The Company is currently evaluating the impact of this guidance and expects to adopt the standard for the annual reporting period ending December 31, 2016.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of its pending adoption of the new standard on the Company's financial statements.

In March 2016, the FASB issued ASU No. 2016-09 *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. This guidance changes the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid-in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. This guidance is effective for annual and interim reporting periods of public entities beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its financial statements.

3. Debt

In May 2014, the Company entered into a $4.5 million loan and security agreement (the "credit facility") with 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 December 2014, the Company drew down the entire $4.5 million. The credit facility had a fixed annual interest rate of 5.50%. On August 4, 2016, the Company repaid in full the entire $4.5 million of outstanding principal and interest under the Loan Agreement between the Company and Square 1 Bank. In connection with such repayment, the Loan Agreement was terminated, and all security, liens or other encumbrances on assets of the Company were released.

The Company incurred $82,685 of loan origination costs related to this credit facility. The remaining unamortized costs of approximately $38,000 were charged to interest expense upon the payment of the loan in August 2016.

In connection with the funding of the term loan, the Company issued to Square 1 a warrant to purchase 22,881 shares of the Company's common stock at an exercise price of $5.90 per share, the closing price of the Company's common stock on the day of funding of the credit facility. During July 2016, Square 1 converted its warrant by a "cashless" conversion and received 9,887 shares of the Company's common stock. The value determined for the warrant at the time of the grant of $108,122 was recorded as a debt discount, as well as to stockholders' equity. The remaining unamortized debt discount associated with the warrant of approximately $59,000 was charged to interest expense upon the payment of the loan in August 2016.

4. Technology Acquisition Agreement

In June 2007, the Company acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor Pharmaceuticals, Inc. ("Questcor") pursuant to an Asset Purchase Agreement. The Company paid Questcor $650,000 in the form of an upfront payment and $500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in the Company's Phase 3 clinical trial for Gimoti. In August 2014, Mallinckrodt, plc ("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 also be required to make additional milestone payments totaling up to $51.5 million. These milestones include up to $4.5 million in payments if Gimoti achieves the following development targets:

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

The remaining $47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, the Company will be required to pay to Mallinckrodt a low single digit royalty on net sales of Gimoti. The Company's obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2030.

5. Stockholders' Equity

Sale of Common Stock and Warrants

On July 25, 2016, the Company completed a registered direct offering of 1,804,512 shares of common stock at a purchase price of $2.49375 per share (the "July 2016 Financing"). Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from the Company an unregistered warrant to purchase three-quarters of a share of common stock, for a total of 1,353,384 shares (the "July Warrants"). The July Warrants have an exercise price of $2.41 per share, are immediately exercisable and will expire on January 25, 2022. The aggregate gross proceeds from the sale of the common stock and warrants were $4.5 million, and the net proceeds after deduction of commissions and fees were $4.0 million.

In connection with the July 2016 Financing, the Company issued to its placement agent, Rodman & Renshaw, a unit of H.C. Wainwright & Co. LLC ("Wainwright"), and its designees unregistered warrants to purchase an aggregate of 90,226 shares of the Company's common stock (the "July Wainwright Warrants"). The July Wainwright Warrants have substantially the same terms as the July Warrants, except that the July Wainwright Warrants will expire on July 21, 2021 and have an exercise price equal to $3.1172 per share of common stock.

On August 3, 2016, the Company completed a registered direct offering of 3,244,120 shares of common stock at a purchase price of $3.0825 per share (the "August 2016 Financing") and together with the July 2016 Financing (the "2016 Financings"). Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from the Company an unregistered warrant to purchase one half of a share of common stock, for a total of 1,622,060 shares (the "August Warrants"). The August Warrants have an exercise price of $3.03 per share, are immediately exercisable and will expire on February 3, 2022. The aggregate gross proceeds from the sale of the common stock and warrants were $10 million, and the net proceeds after deduction of commissions and fees was approximately $9.2 million.

In connection with the August 2016 financing, the Company issued to its placement agent, Wainwright, and its designees unregistered warrants to purchase an aggregate of 162,206 shares of the Company's common stock (the "August Wainwright Warrants"). The August Wainwright Warrants have substantially the same terms as the August Warrants, except that the August Wainwright Warrants will expire on July 29, 2021 and have an exercise price equal to $3.853125 per share of common stock.

The warrants issued in connection with the 2016 Financings had a total initial fair value of $4,899,459 on their respective closing dates as determined using the Black Scholes pricing model and such value was recorded as the initial carrying value of the warrant liability. The fair value of the warrants is remeasured at each financial reporting period with any change in fair value recognized as a change in fair value of the warrant liability in the Statement of Operations.

At the Market Equity Offering Program

In November 2014, the Company entered into an At Market Sales Agreement with MLV & Co. LLC ("MLV") ("MLV Sales Agreement"), pursuant to which the Company could sell from time to time, at its option, up to an aggregate of $6.6 million worth of shares of common stock through MLV as sales agent. During September 2015, FBR & Co. ("FBR"), acquired MLV. The sales of shares of the Company's common stock made through this equity program were made in "at-the-market" offerings as defined in Rule 415 of the Securities Act of 1933, as amended (the "Securities Act"). During the year ended December 31, 2015, the Company sold 1,048,507 shares of common stock at a weighted average price per share of $4.78 pursuant to the MLV Sales Agreement and received proceeds of approximately $4.9 million, net of commissions and fees. The Company did not sell any shares of common stock through the MLV Sales Agreement during 2016. The Company incurred approximately $138,000 of legal, accounting and filing fees related to its Registration Statement on Form S-3 filed in November 2014. Such costs were capitalized and included in other current assets at December 31, 2014, and were reclassified to additional paid-in capital during the first quarter of 2015 as a further offset to the net proceeds.

On April 15, 2016, the Company terminated the MLV Sales Agreement and entered into a new At Market Issuance Sales Agreement with FBR ("FBR Sales Agreement"), pursuant to which the Company may sell from time to time, at its option, up to an aggregate of 649,074 shares of the Company's common stock through FBR as the sales agent. The sales of shares made through this equity program are made in "at-the-market" offerings as defined in Rule 415 of the Securities Act. Through September 30, 2016, the Company has sold 56,000 shares of common stock at a weighted average price per share of $5.45 and received proceeds of approximately $296,000, net of commissions and fees. Future sales will depend on a variety of factors including, but not limited to, market conditions, the trading price of the Company's common stock and the Company's capital needs. Although sales of the Company's common stock have taken place pursuant to the MLV Sales Agreement, and are continuing pursuant to the FBR Sales Agreement, there can be no assurance that FBR will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that the Company deems appropriate.

In addition, the Company will not be able to make future sales of common stock pursuant to the FBR Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to FBR under the FBR Sales Agreement. Furthermore, FBR is permitted to terminate the FBR 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 the Company's assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations. Finally, under the Securities Purchase Agreements entered into in connection with the 2016 Financings, the Company agreed to not sell any shares of its common stock for a period through and including September 17, 2016, without prior consent by the 2016 Financings investors. The Company has no obligation to sell the remaining shares available for sale pursuant to the FBR Sales Agreement.

Employee Stock Purchase Plan and Equity Incentive Award Plan

As a result of payroll withholdings from the Company's employees of approximately $99,000 and $170,000, the Company sold 34,067 and 41,176 shares of common stock through its ESPP during the nine months ended September 30, 2016 and 2015, respectively.

On April 27, 2016, the Company's stockholders approved an amendment and restatement of the Company's 2013 Equity Incentive Award Plan (the "Restated Plan") to increase the number of shares of common stock reserved under the Restated Plan by 500,000 shares, to an aggregate of 4,786,425 shares, and to extend the term of the Restated Plan into 2026.

Stock-Based Compensation

Stock-based compensation expense includes charges related to stock option grants and employee stock purchases under the ESPP. 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, 2016 and 2015:

	Three and Nine Months Ended September 30,	
	2016	**2015**
Common Stock Options		
Risk free interest rate	1.25% - 1.58%	l.50% - 1.87%
Expected option term	5.3 - 6.0 years	5.5 - 6.0 years
Expected volatility of common stock	74.44 - 75.91%	71.99% - 76.74%
Expected dividend yield	0.0%	0.0%

The estimated fair value of each ESPP award 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, 2016 and 2015:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Employee Stock Purchase Plan				
Risk free interest rate	0.47%	0.26%	0.47% - 0.50%	0.08% - 0.26%
Expected term	6 months	6 months	6 months	6 months
Expected volatility of common stock	212.80%	69.64%	83.83% - 212.80%	62.91% - 69.64%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

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,	
	2016	**2015**	**2016**	**2015**
Research and development	$ 177,767	$ 144,719	$ 487,704	$ 433,252
General and administrative	274,469	226,956	810,575	694,561
Total stock-based compensation expense	$ 452,236	$ 371,675	$ 1,298,279	$ 1,127,813

In February 2016, the Company effected a one-time option exchange, wherein employees were offered the opportunity to exchange certain outstanding stock options for the grant of a lesser number of replacement stock options. The participants received three new stock options for every four stock options tendered for exchange. As a result, 703,500 stock options were exchanged for 527,624 replacement stock options. The replacement stock options have a three-year vesting schedule and an exercise price of $3.04 per share, which was the closing price of the Company's common stock on the date of the option exchange. All other terms of the replacement stock options remain the same as the original stock options that were exchanged. As a result of this transaction, the Company recognized an incremental stock-based compensation expense of approximately $4,700 at the time of the transaction and will recognize an additional approximately $141,000 of stock-based compensation expense over the three-year vesting term of the exchanged options.

As of September 30, 2016, there were approximately $2.2 million of unrecognized compensation costs related to outstanding employee and board of director options, which are expected to be recognized over a weighted average period of 1.03 years.

6. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

During the year ended December 31, 2015, the Company had no assets or liabilities requiring fair value measurements. As noted in Note 5, during the third quarter of 2016 the Company entered into the 2016 Financings with an institutional investor providing for the issuance and sale by the Company of 5,048,632 shares of the Company's common stock and warrants to purchase up to 2,975,444 shares of the Company's common stock for aggregate gross proceeds of $14.5 million. In addition, as partial payment for services, the Company issued to the underwriters warrants to purchase up to 252,432 shares of the Company's common stock.

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The Company had no assets or liabilities classified as Level 1 or Level 2. The warrant liability is classified as Level 3.

The Company has classified the warrants as a liability and has remeasured the liability to estimated fair value at September 30, 2016, using the Black Scholes option pricing model with the following assumptions:

	September 30, 2016
Risk-free interest rate	1.14%
Expected volatility	92.76% - 96.19%
Expected term	4.83 years - 5.33 years
Expected dividend yield	0%

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2016:

	Fair Value Measurement as of September 30, 2016			
	Level 1	Level 2	Level 3	Balance
Warrant liability	$ -	$ -	$ 5,098,404	$ 5,098,404
Total	$ -	$ -	$ 5,098,404	$ 5,098,404

The following table presents a reconciliation of the Company's liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the nine months ended September 30, 2016:

	Warrant Liability
Balance at December 31, 2015	$ -
Issuance of warrants	4,899,459
Change in fair value upon re-measurement	198,945
Balance at September 30, 2016	$ 5,098,404

There were no transfers between Level 1 and Level 2 in any of the periods reported.

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, 2015 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 10, 2016. 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 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," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar 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.

We use our registered trademark, EVOKE PHARMA, and our trademarked product name, Gimoti, in this Quarterly Report on Form 10-Q. Solely for convenience, trademarks and tradenames referred to in this Quarterly Report on Form 10-Q appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

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 disorders and diseases. We are developing Gimoti (formerly known as EVK-001), a metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. Diabetic gastroparesis is a gastrointestinal 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 the symptoms associated with diabetic gastroparesis, and is currently available only in oral and intravenous forms. Gimoti is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through nasal administration.

Gastroparesis is a condition of delayed gastric emptying in the absence of mechanical obstruction. Gastroparesis results in food remaining in the stomach for a longer time than normal, yielding a variety of symptoms and systemic metabolic complications. Gastroparesis is a common problem in individuals with diabetes, but also is observed in patients with prior gastric surgery, a preceding infectious illness, pseudo-obstruction, collagen vascular disorders and anorexia nervosa. According to the American Motility Society Task Force on Gastroparesis, the prevalence of gastroparesis is estimated to be up to 4% of the United States population. Signs and symptoms of gastroparesis include nausea, early satiety, prolonged fullness, bloating, upper abdominal pain, vomiting and retching. The disorder can lead to considerable pain and discomfort, poor nutrition, impaired glycemic control and diminished quality of life.

We believe nasal administration has the potential to provide our target population of female diabetic gastroparesis patients with a preferred treatment option for several important reasons: (1) unlike metoclopramide tablets which may have erratic absorption due to gastroparesis itself, Gimoti is designed to bypass the digestive system to allow for more predictable drug absorption, even when

patients are vomiting; (2) the absorption of Gimoti occurs across the thin mucosa in the nasal cavity to allow for rapid and predictable drug administration through the nasal route; and (3) for gastroparesis patients experiencing nausea, a nasal spray may be better tolerated than an oral medication.

We have evaluated Gimoti in a multicenter, randomized, double-blind, placebo-controlled parallel group, dose-ranging Phase 2b clinical trial in 287 subjects with diabetic gastroparesis where Gimoti 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 enrollment in a Phase 3 clinical trial of Gimoti in female subjects with symptoms associated with acute and recurrent diabetic gastroparesis. This Phase 3 clinical trial was a multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluating the efficacy, safety and population pharmacokinetics of Gimoti in adult female subjects with diabetic gastroparesis when dosed four times a day for 28 days. A total of 205 subjects were randomized in this trial. Preliminary results of the trial showed that Gimoti did not achieve its primary endpoint of symptom improvement at Week 4.

Preliminary review of topline data across all study sites revealed similar improvement in the Gimoti and placebo groups at Week 4 as measured by the total symptom score, as well as the individual scores for each of the signs and symptoms. Additional analyses of the datasets and pharmacokinetic, or PK, data is being conducted to further understand the discrepant results.

Safety results were consistent with findings from previous Gimoti studies that showed the nasal formulation of metoclopramide has a favorable safety profile and is well-tolerated by healthy volunteers and patients with diabetic gastroparesis. In this Phase 3 study, there were slightly more reports of nasal irritation in subjects receiving placebo than in subjects receiving Gimoti.

The study was a U.S.-based, multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial to evaluate the efficacy, safety and population PK of Gimoti in 205 adult female subjects with diabetic gastroparesis who received Gimoti or placebo four times daily for four weeks. The primary endpoint was the change in symptoms from the baseline period to Week 4 as measured using a proprietary Patient Reported Outcome, or PRO, instrument. The PRO was used to calculate a weekly score based on daily telephone diary entries by study subjects who reported the frequency and severity of their gastroparesis signs and symptoms.

In September 2016, we announced that we had completed a pre-New Drug Application, or NDA, meeting with the U.S. Food and Drug Administration, or FDA. The purpose of the meeting was to discuss a proposed NDA and to confirm various regulatory, chemistry, manufacturing, and control, or CMC, non-clinical requirements for our potential Gimoti NDA submission. At the pre-NDA meeting, representatives from the FDA reviewed a portion of our data package being prepared for the NDA submission. Based on the review, discussion, and minutes received, it was determined that the available data would be sufficient for submission of that portion of an NDA utilizing the 505(b)(2) pathway, with acceptance of the final NDA subject to their review of the complete package.

In 2014, we also completed a thorough ECG (QT/QTc) study and reported positive results in December 2014. Prolongation of the QT interval may increase the risk for cardiac arrhythmias. Data from the thorough ECG (QT/QTc) trial met the pre-specified primary endpoint, demonstrating that Gimoti, at therapeutic and supratherapeutic doses, did not prolong the QT/QTc interval in healthy subjects.

We have also conducted a companion clinical trial with Gimoti in male subjects with symptoms associated with acute and recurrent diabetic gastroparesis to assess the safety and efficacy of Gimoti in men. The male companion trial was initiated in May 2014 and the design was the same as the Phase 3 trial in women. This trial was requested by the FDA to confirm the Phase 2b trial results and to capture additional safety data in men. This trial was not required for submission of the Gimoti NDA for women; however, we expect to include safety data from this trial in the NDA submission. During November 2016, we determined the trial showed futility so that, even if the trial had fully been enrolled, the results would not have differed. As we anticipated at the beginning of the trial, based on the prior Phase 2b data, the results showed no statistical significant efficacy in men and the safety profile for Gimoti was favorable compared to placebo with good tolerability.

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, borrowings under our loan and security agreements and the sale of shares of our common stock on the NASDAQ Capital Market. We have incurred losses in each year since our inception. Substantially all of our operating losses resulted from expenses incurred in connection with advancing Gimoti 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.

As of September 30, 2016 we had cash and cash equivalents of $10.4 million. In addition to our normal operations, during the three months ended September 30, 2016 we received net proceeds of approximately $13.2 million from our sale of common stock and

warrants in July and August 2016, or 2016 Financings and repaid in full on August 4, 2016 the entire $4.5 million of outstanding principal and interest under the Loan and Security Agreement, dated as of May 28, 2014, as amended, or the Loan Agreement, between us and Square 1 Bank, a division of Pacific Western Bank, or Square 1, as lender. In connection with such repayment, the Loan Agreement was terminated, and all security, liens or other encumbrances on assets of ours were released. We believe our existing cash and cash equivalents will be sufficient to fund our operations through at least June 30, 2017. Current funds on hand are intended to permit us to conduct further analyses of the Phase 3 trial data of Gimoti and assess continued development opportunities for this product candidate, to prepare for a meeting with the FDA and for other working capital and other general corporate purposes.

Technology Acquisition Agreement

In June 2007, we acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor Pharmaceuticals, Inc., or Questcor, pursuant to an asset purchase agreement. We paid Questcor $650,000 in the form of an upfront payment and $500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in our Phase 3 clinical trial for Gimoti. 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 us 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 Gimoti achieves the following development targets:

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

The remaining $47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, we will be required to pay to Mallinckrodt a low single digit royalty on net sales of Gimoti. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, 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 Gimoti. With the completion of our Phase 3 clinical trial in women and the companion trial in men using Gimoti, we expect our research and development expenses to decrease for the remainder of 2016 as we conduct further analyses of the Phase 3 trial data and assess continued development opportunities. 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 Gimoti. 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 subjects;
- the number of subjects that participate in the trials;
- the number of doses that subjects receive;
- the cost of comparative agents used in trials;

- the drop-out or discontinuation rates of subjects;
- 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 yet know when Gimoti may be commercially available, if at all.

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, including fees associated with investor relations and directors and officers liability insurance premiums. We expect that general and administrative expenses will remain consistent for the remainder of the year.

Other Expenses

Other expenses consist of changes in the fair value of the warrant liability, which represents the change in the fair value of common stock warrants from the date of issuance to the end of the reporting period. The warrant liability will be revalued each reporting period until the liability is settled. We use the Black Scholes pricing model to value the related warrant liability. In addition, costs associated with the issuance of common stock warrants were recorded as an other expense upon issuance. Other expense also consists of interest expense incurred on our former outstanding debt.

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 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.

The critical accounting policies and estimates underlying the accompanying unaudited financial statements are those set forth in Part II, Item 7 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, which was filed with the SEC on March 10, 2016, and additionally the following accounting policy for warrants.

Warrant Accounting

Since the warrants to purchase shares of our common stock that were issued as a part of the 2016 Financing contain a feature that could require the transfer of cash in the event a change in control occurs without the authorization of our Board of Directors, we classified these warrants as a liability on our balance sheet. The warrants were initially recorded at fair value on the date of grant using the Black Scholes pricing model and they are subsequently remeasured to fair value at each subsequent balance sheet date. Changes in fair value of the warrants are recognized as a component of other expense in the Statement of Operations. We will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants.

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.

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 initial public offering, or 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 SEC.

Results of Operations

Comparison of Three Months Ended September 30, 2016 and 2015

The following table summarizes the results of our operations for the three months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Increase/ (Decrease)
	2016	2015	
Research and development	$ 1,339,343	$ 1,837,743	$ (498,400)
General and administrative	$ 830,092	$ 819,703	$ 10,389
Other expense	$ 855,846	$ 77,954	$ 777,892

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 decreased by approximately $498,000 due primarily to the completion of the Phase 3 clinical trial and the transition to analysis of the trial data. Costs incurred in 2016 include approximately $650,000 related to our ongoing clinical trials and approximately $489,000 for wages, taxes and employee insurance, including approximately $178,000 of stock-based compensation expense and approximately $193,000 related to costs associated with the preparation of an NDA. Costs incurred in 2015 include approximately $1.3 million related to the clinical trials for Gimoti and approximately $495,000 for wages, taxes and employee insurance, including approximately $145,000 of stock-based compensation expense.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 increased by approximately $10,000. Costs incurred in 2016 primarily included approximately $446,000 for wages, taxes and employee insurance, including approximately $274,000 of stock-based compensation expense and approximately $319,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. Costs incurred in 2015 primarily included approximately $424,000 for wages, taxes and employee insurance, including approximately $227,000 of stock-based compensation expense, and approximately $302,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

Other Expenses. Other expenses increased by approximately $778,000 due primarily to the expensing of approximately $534,000 of costs related to the 2016 Financings and to the increase of approximately $199,000 in the fair value of the warrant liability for the three months ended September 30, 2016. The warrants were initially valued at $4.9 million in connection with our sale of securities through the 2016 Financings. Additional other expense for the three months ended September 30, 2016 and 2015 consists of interest expense incurred on our former outstanding debt.

Comparison of Nine Months Ended September 30, 2016 and 2015

The following table summarizes the results of our operations for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,		Increase/ (Decrease)
	2016	2015	
Research and development	$ 5,449,568	$ 6,445,842	$ (996,274)
General and administrative	$ 2,770,500	$ 2,821,382	$ (50,882)
Other expense	$ 1,001,120	$ 230,087	$ 771,033

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 decreased by approximately $996,000 due primarily to the completion of the Phase 3

clinical trial and the transition to analysis of the trial data. Costs incurred in 2016 include approximately $3.1 million related to our ongoing clinical trials, approximately $1.5 million for wages, taxes and employee insurance, including approximately $488,000 of stock-based compensation expense, and approximately $740,000 related to costs associated with the preparation of an NDA. Costs incurred in 2015 include approximately $4.6 million related to our ongoing clinical trials, approximately $1.6 million for wages, taxes and employee insurance, including approximately $433,000 of stock-based compensation expense, and approximately $238,000 related to stability testing and the completion of the production of a commercial-size batch of Gimoti.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 decreased by approximately $51,000. Costs incurred in 2016 primarily included approximately $1.5 million for wages, taxes and employee insurance, including approximately $811,000 of stock-based compensation expense and approximately $1.1 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. Costs incurred in 2015 primarily included approximately $1.3 million for wages, taxes and employee insurance, including approximately $695,000 of stock-based compensation expense, approximately $1.1 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company and approximately $187,000 for market research activities.

Other Expenses. Other expenses increased by approximately $771,000 due primarily to the expensing of approximately $534,000 of costs related to the 2016 Financings and to the increase of approximately $199,000 in the fair value of the warrant liability for the nine months ended September 30, 2016. The warrants were initially valued at $4.9 million in connection with our sale of securities through the 2016 Financings. Additional other expense for the nine months ended September 30, 2016 and September 30, 2015, consists of interest expense incurred on our former outstanding debt.

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.

In July 2016, we completed an at-the-market offering of 1,804,512 shares of common stock at a purchase price of $2.49375 per share, or the July 2016 Financing. Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received an unregistered warrant to purchase three-quarters of a share of our common stock, for a total of 1,353,384 shares, or the July Warrants. The July Warrants have an exercise price of $2.41 per share, are immediately exercisable and will expire on January 25, 2022. The aggregate gross proceeds from the sale of the common stock and warrants were $4.5 million, and the net proceeds after deduction of commissions and fees were approximately $4.0 million.

In connection with the July 2016 Financing, we issued to our placement agent, Rodman & Renshaw, a unit of H.C. Wainwright & Co. LLC, or Wainwright, and its designees unregistered warrants to purchase an aggregate of 90,226 share of our common stock, or the July Wainwright Warrants. The July Wainwright Warrants have substantially the same terms as the July Warrants, except that the July Wainwright Warrants will expire on July 21, 2021 and have an exercise price equal to $3.1172 per share of common stock.

In August 2016, we completed an at-the-market offering of 3,244,120 shares of common stock at a purchase price of $3.0825 per share, the August 2016 Financing. Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from an unregistered warrant to purchase one half of a share of our common stock, for a total of 1,622,060 shares, or August Warrants. The August Warrants have an exercise price of $3.03 per share, are immediately exercisable and will expire on February 3, 2022. The aggregate gross proceeds from the sale of the common stock and warrants were $10.0 million, and the net proceeds after deduction of commissions and fees were approximately $9.2 million.

In connection with the August 2016 Financing, we issued to our placement agent, Wainwright, and its designees unregistered warrants to purchase an aggregate of 162,206 shares of our common stock, or the August Wainwright Warrants. The August Wainwright Warrants have substantially the same terms as the August Warrants, except that the August Wainwright Warrants will expire on July 29, 2021 and have an exercise price equal to $3.853125 per share of common stock.

In May 2014, we entered into a $4.5 million loan and security agreement, the credit facility with 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 December 2014, we drew down the entire $4.5 million. The credit facility had a fixed annual interest rate of 5.50%. On August 4, 2016, we repaid in full the entire $4.5 million of outstanding principal and interest under the Loan and Security Agreement, dated as of May 28, 2014, as amended, or the Loan Agreement, between us and Square 1. In connection with such repayment, the Loan Agreement was terminated, and all security, liens or other encumbrances on assets of ours were released.

We incurred $82,685 of loan origination costs related to this credit facility. The remaining unamortized costs of approximately $38,000 were charged to interest expense upon the payment of the loan in August 2016.

In connection with the funding of the term loan, we issued to Square 1 a warrant to purchase 22,881 shares of our common stock at an exercise price of $5.90 per share, the closing price of our common stock on the day of funding of the credit facility. During July 2016, Square 1 converted its warrant by a "cashless" conversion and received 9,887 shares of our common stock. The value determined for the warrant at the time of the grant of $108,122 was recorded as a debt discount, as well as to stockholders' equity. The remaining unamortized debt discount associated with the warrant of approximately $59,000 was charged to interest expense upon the payment of the loan in August 2016.

We have incurred losses since inception and have negative cash flows from operating activities. As of September 30, 2016, we had approximately $10.4 million in cash and cash equivalents and working capital of approximately $9.8 million.

We expect to continue to incur expenses and increase operating losses for at least the next several years. In the near-term, we anticipate incurring costs as we:

- continue our analyses of the results of our Phase 3 clinical trial with Gimoti in women and also complete our analysis of the companion clinical trial in men in preparation for a meeting with the FDA;
- continue the preparation of the commercial manufacturing process;
- 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 to fund our operations through at least June 30, 2017, it will not be sufficient to complete any additional development requirements requested by the FDA. Accordingly, we will continue to require substantial additional capital beyond our current cash and cash equivalents to continue our clinical and regulatory development and potential commercialization activities. The amount and timing of our future funding requirements will depend on many factors further discussed below, including any feedback from the FDA on the scope of any additional clinical development requirements. 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.

In November 2014, we entered into a sales agreement with MLV & Co., LLC, or the MLV Sales Agreement, which was subsequently acquired by FBR & Co., or FBR, pursuant to which we were able to sell from time to time, at our option, up to an aggregate of $6.6 million worth of shares of common stock through MLV, as sales agent. The sales of shares of our common stock made through this equity program were made in "at-the-market" offerings as defined in Rule 415 of the Securities Act. During the year ended December 31, 2015, we sold 1,048,507 shares of common stock at a weighted average price per share of $4.78 pursuant to the MLV Sales Agreement and received proceeds of approximately $4.9 million, net of commissions and fees. We did not sell any shares of common stock through the MLV Sales Agreement during 2016.

On April 15, 2016, we terminated the MLV Sales Agreement and entered into a new At Market Issuance Sales Agreement with FBR, or the FBR Sales Agreement, pursuant to which we may sell from time to time, at our opinion, up to an aggregate of 649,074 shares of our common stock through FBR as the sales agent. Through September 30, 2016, we have sold 56,000 shares of common stock and received net proceeds of approximately $296,000 under the FBR Sales Agreement. At October 31, 2016, we have the capacity to sell an additional 593,074 shares of common stock under the FBR Sales Agreement. Future sales will depend on a variety of factors including, but not limited to, market conditions, the trading price of our common stock and our capital needs.

Although sales of our common stock have taken place pursuant to the MLV Sales Agreement and are continuing pursuant to the FBR Sales Agreement, there can be no assurance that FBR will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate.

We will not be able to make future sales of our common stock pursuant to the FBR Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to FBR under the FBR Sales Agreement. Furthermore, FBR is permitted to terminate the FBR 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. We have no obligation to sell the remaining shares available for sale pursuant to the FBR Sales Agreement.

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 their report on our financial statements as of and for the year ended December 31, 2015 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 also 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, we expect to be able to fund our operations through at least June 30, 2017. This period could be shortened if there are any significant increases in planned spending on our Gimoti development program. 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.

The following table summarizes our cash flows for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
	2016	**2015**
Net cash used in operating activities	$ (7,338,098)	$ (8,043,365)
Net cash provided by financing activities	$ 9,026,825	$ 4,626,373
Net increase (decrease) in cash and cash equivalents	$ 1,688,727	$ (3,416,992)

Operating Activities. The primary use of our cash has been to fund our clinical research and other general operations.

Financing Activities. During the nine months ended September 30, 2016, we received net proceeds of approximately $358,000 from the sale of 56,000 shares of common stock pursuant to the FBR Sales Agreement and the sale of 34,067 shares of common stock through our employee stock purchase plan. In addition, through the 2016 Financings, we received net proceeds of approximately $13.2 million from the sale of 5,048,632 shares of common stock and 2,975,444 warrants to purchase our common stock. During the nine months ended September 30, 2015, we received net proceeds of approximately $4.6 million from the sale of 932,237 shares of common stock pursuant to the MLV Sales Agreement and the sale of 41,176 shares of common stock through our employee stock purchase plan.

We believe that our existing cash and cash equivalents as of September 30, 2016, together with interest thereon, will be sufficient to meet our anticipated cash requirements through at least June 30, 2017. 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 results of our continuing analysis of topline data from our Phase 3 trial, and our assessment of continued clinical and regulatory development opportunities for Gimoti, including any feedback received from the FDA;
- the need for, and the progress, costs and results of, any additional clinical trials of Gimoti we may initiate based on the results of our completed Phase 3 trial or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of Gimoti;
- 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 Gimoti 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 Gimoti;

- 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, 2016, 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

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.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

As of September 30, 2016, 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, 2015.

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, 2016.

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, 2015, 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, Gimoti

Our business is entirely dependent on the success of Gimoti, which recently failed to achieve the primary endpoint of symptom improvement in a Phase 3 clinical trial in female patients with symptoms associated with diabetic gastroparesis. While we are continuing to assess the topline data from the trial, we may be unable to identify a viable path forward for continued development of this product candidate. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, Gimoti.

To date, we have devoted all of our research, development and clinical efforts and financial resources toward the development of Gimoti, our patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women. Gimoti is our only product candidate. On July 18, 2016, we announced topline results from our Phase 3 clinical trial that evaluated the efficacy and safety of Gimoti in women with symptoms associated with diabetic gastroparesis. In this study, Gimoti did not achieve its primary endpoint of symptom improvement at Week 4.

While we are performing additional analyses of data from this Phase 3 trial and will meet with the U.S. Food and Drug Administration, or FDA, to discuss potential paths forward for continued development of Gimoti, we may be unable to salvage any value from the Phase 3 trial and may be unable to identify a viable plan for continued clinical development of this product candidate. In September 2016, we announced that we had completed a pre-New Drug Application, or NDA, meeting with the FDA, focused on the content of the regulatory, chemistry, manufacturing, and control, or CMC, and non-clinical sections of our planned NDA filing for Gimoti. Based on the FDA's response to the information package we submitted prior to the meeting and the meeting discussion, we believe we now have the information needed to complete the CMC sections of the NDA in a manner that will be acceptable for the FDA's review of the complete NDA package. We cannot provide any assurance as to the timing of any such future FDA meeting to discuss the clinical requirements for NDA submission, or if the meeting results will allow us to identify a path forward for continued clinical development or regulatory approval of Gimoti. Even if we are able to design further trials and identify a path forward toward potential regulatory approval of Gimoti, the development will likely require significant financial and personnel resources. Furthermore, we experienced patient recruitment, enrollment and dropout challenges in our recently-completed Phase 3 trial, and given the negative results from this recent trial, we could experience even more significant obstacles in any further clinical development of Gimoti.

There can be no assurance that we will be able to further develop Gimoti. Our continuing analyses of data from the topline Phase 3 trial may produce negative or inconclusive results, or may be inconsistent with our previously announced topline results. Because our business is entirely dependent on the success of Gimoti, if we are unable to identify, fund and ultimately execute an alternative development strategy for this product candidate, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in the complete loss of an investment in our securities.

In addition to the above factors, the future regulatory and commercial success of Gimoti is subject to a number of additional risks, including the following:

- we may not have sufficient financial and other resources to complete clinical development for Gimoti;
- we may not be able to provide acceptable evidence of safety and efficacy for Gimoti;
- the FDA may disagree with the design of our future clinical trials, if any are necessary;
- variability in subjects, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;
- the FDA may not agree with the analysis of our clinical trial results;

- the results of our clinical trials 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 Gimoti before we can submit an NDA, to the FDA or receive approval of the NDA;
- subjects in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to Gimoti, such as dysgeusia, headache, diarrhea, nasal discomfort, tremor, myoclonus, somnolence, rhinorrhea, throat irritation, and fatigue;
- if approved, Gimoti 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 Gimoti;
- 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 Gimoti, 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 liquidate, dissolve or otherwise wind down our operations.

Our operations have consumed substantial amounts of cash since inception. We believe, based on our current operating plan, that our existing cash and cash equivalents will be sufficient to fund our operations through at least June 30, 2017, although there can be no assurance in that regard. We will be required to raise additional funds in order to continue as a going concern.

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 results of our continuing analysis of topline data from our Phase 3 trial and our assessment of continued development opportunities for Gimoti, including any feedback received from the FDA;
- the need for, and the progress, costs and results of, any additional clinical trials of Gimoti we may initiate based on the results of our completed Phase 3 trial or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of Gimoti;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from the FDA, and any similar regulatory agencies;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Gimoti;
- the costs and timing of completion of outsourced commercial manufacturing supply arrangements for Gimoti; and
- costs associated with any other product candidates that we may develop, in-license or acquire.

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. Furthermore, the issuance of additional shares or other securities 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. We cannot provide any assurance that our existing capital resources will be sufficient to enable us to identify or execute a viable plan for continued clinical development of Gimoti or to otherwise survive as a going concern.

Any termination or suspension of, or delays in the completion of, any future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Delays in the completion of any future clinical trials for Gimoti could significantly affect our product development costs. We do not know whether any trials will produce data 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 placing the clinical trial on hold;
- subjects failing to remain in our trial at the rate we expect (for example, due to variable patient frequency and severity of disease and variability in gastric emptying testing);
- subjects choosing an alternative treatment for the indication for which we are developing Gimoti, or participating in competing clinical trials;
- subjects experiencing severe or unexpected drug-related adverse effects;
- a facility manufacturing Gimoti, 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 the FDA's current good manufacturing practices 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 independent 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 Gimoti, 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 Gimoti could be significantly reduced.

Delays in the completion of any other clinical trials and studies we may conduct for Gimoti could be harmful to our business and cause us to require additional funding.

We could be subject to securities class action litigation.

As a result of our announcement of negative results in our Phase 3 clinical trial on July 18, 2016, our stock price declined substantially. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could further harm our business.

If we fail to continue to meet all applicable Nasdaq Capital Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is listed on the Nasdaq Capital Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum price per share and continued business operations so that we are not characterized as a "public shell company." If we are unable to comply with Nasdaq's listing standards, Nasdaq may determine to delist our common stock from the Nasdaq Capital Market. In the event that our common stock is delisted from the Nasdaq Capital Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

As a result of the negative results from the Phase 3 trial and our limited financial resources, we may not be successful in retaining key employees.

Our cash conservation activities may yield unintended consequences, such as reduced employee morale and unwanted attrition. Competition among biotechnology companies for qualified employees is intense, and the ability to retain our key employees is critical to our ability to effectively manage our resources while we seek to identify a viable path forward for continued development of Gimoti. Loss of any of our key employees could have a material adverse effect on our business.

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 Gimoti.

We will require substantial additional future capital in order to finance any additional development activities for Gimoti, including any requirements requested by the FDA, as well as for any NDA preparation and pre-commercial activities, including marketing and manufacturing of Gimoti. The amount and timing of any expenditure needed to implement our development and commercialization programs will depend on numerous factors, including:

- the results of our continuing analysis of topline data from our Phase 3 trial, and our assessment of continued development opportunities for Gimoti, including any feedback received from the FDA;
- the need for, and the progress, costs and results of, any additional clinical trials of Gimoti we may initiate based on our completed Phase 3 trial or discussions with the FDA, including any additional trials the FDA or other regulatory agencies may require evaluating the safety of Gimoti;
- 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 Gimoti 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 Gimoti;
- 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 will be sufficient to enable us to fund any additional clinical development of Gimoti, and, in any event, we will need to raise additional capital to complete such clinical development and submit marketing applications for and prepare for commercialization of Gimoti should we receive product approval. We may need to raise additional funds in the near future to complete development activities for Gimoti.

We may seek additional funding through collaboration agreements and public or private financings. For example, in April 2016 we entered into the FBR Sales Agreement, pursuant to which we may sell from time to time, at our option, up to an aggregate of 649,074 shares of our common stock through FBR, as sales agent. Sales of our common stock made pursuant to the FBR Sales Agreement are made on The NASDAQ Capital Market under our shelf registration statement on Form S-3 filed on November 13, 2014, which was declared effective by the SEC on November 25, 2014, by means of ordinary brokers' transactions at market prices. Although sales of our common stock have taken place pursuant to the MLV Sales Agreement, there can be no assurance that FBR will be successful in consummating future 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 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 FBR Sales Agreement, is limited to an aggregate of one-third of our public float. Furthermore, FBR 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 additional clinical development of Gimoti 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

Unregistered Sales of Equity Securities

July 2016 Financing

On July 25, 2016, in a private placement we issued warrants to purchase 1,353,384 shares of our common stock to certain institutional investors in a concurrent SEC-registered offering of common stock. The warrants were sold at a price of $0.09375 per share of common stock issuable upon exercise of the warrants, or the July Warrants. The July Warrants are immediately exercisable at an exercise price equal to $2.41 per share of common stock and expire on January 25, 2022. Subject to limited exceptions, a holder of July Warrants will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise.

Also on July 25, 2016, in a private placement we issued warrants to purchase 90,226 shares of our common stock to Rodman & Renshaw, a unit of H.C. Wainwright & Co. LLC, in compensation for its services as a placement agent in connection with a concurrent SEC-registered offering and a private placement, or the July Wainwright Warrants. The July Wainwright Warrants are immediately exercisable at an exercise price equal to $3.1172 per share of common stock and expire on July 21, 2021.

The issuances of the July Warrants and the July Wainwright Warrants were deemed exempt from registration under Section 4(a)(2) or Regulation D of the Securities Act. The recipients of securities in the transactions exempt under Section 4(a)(2) or Regulation D of the Securities Act represented their intention to acquire the securities for investment purposes only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the instruments issued in such transactions.

August 2016 Financing

On August 3, 2016, in a private placement we issued warrants to purchase 1,622,060 shares of our common stock to certain institutional investors in a concurrent SEC-registered offering of common stock. The warrants were sold at a price of $0.0625 per share of common stock issuable upon exercise of the warrants, or the August Warrants. The August Warrants are immediately exercisable at an exercise price equal to $3.03 per share of common stock and expire on February 3, 2022. Subject to limited exceptions, a holder of August Warrants will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to such exercise.

Also on August 3, 2016, in a private placement we issued warrants to purchase 162,206 shares of our common stock to Rodman & Renshaw, a unit of H.C. Wainwright & Co. LLC, in compensation for its services as a placement agent in connection with a concurrent SEC-registered offering and a private placement, or the August Wainwright Warrants. The August Wainwright Warrants are immediately exercisable at an exercise price equal to $3.853125 per share of common stock and expire on July 29, 2021.

The issuances of the August Warrants and the August Wainwright Warrants were deemed exempt from registration under Section 4(a)(2) or Regulation D of the Securities Act. The recipients of securities in the transactions exempt under Section 4(a)(2) or Regulation D of the Securities Act represented their intention to acquire the securities for investment purposes only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the instruments issued in such transactions.

Warrant Exercise

In July 2016, Square 1 converted its warrant to purchase shares of our common stock by a “cashless” exercise and received 9,887 shares of our common stock. The warrant had an exercise price of $5.90 per share. The shares sold were sold in reliance upon the registration exemption set forth in Section 4(a)(2) of the Securities Act of 1933, as amended.

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 9, 2016

By: /s/ David A. Gonyer
David A. Gonyer
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2016

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 issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated July 20, 2016
4.6 (5)	Form of Warrant issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated July 29, 2016
10.1 (4)	Form of Securities Purchase Agreement dated as of July 20, 2016 by and between the Company and certain investors party thereto
10.2 (4)	Engagement Letter dated as of July 19, 2016 by and between the Company and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC
10.3 (5)	Form of Securities Purchase Agreement dated as of July 29, 2016 by and between the Company and certain investors party thereto
10.4 (5)	Engagement Letter dated as of July 29, 2016 by and between the Company and Rodman & Renshaw, a unit of H.C. Wainwright & 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
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 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 July 20, 2016.
(5) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2016.
Management contract or compensatory plan or arrangement.

* 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 Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David A. Gonyer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Evoke Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

/s/ David A. Gonyer
David A. Gonyer
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew J. D'Onofrio, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Evoke Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

/s/ Matthew J. D'Onofrio
Matthew J. D'Onofrio
Executive Vice President, Chief Business Officer,
Treasurer and Secretary
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Evoke Pharma, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David A. Gonyer, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2016

/s/ David A. Gonyer
David A. Gonyer
President and Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Evoke Pharma, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew J. D'Onofrio, Executive Vice President, Chief Business Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2016

/s/ Matthew J. D'Onofrio
Matthew J. D'Onofrio
Executive Vice President, Chief Business Officer, Treasurer and Secretary

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.