Evoke Pharma Inc
Form 10-Q
November 13, 2018

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, 2018

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 (State or other jurisdiction of incorporation)	20-8447886 (IRS Employer Identification No.)
420 Stevens Avenue, Suite 370, Solana Beach, CA (Address of principal executive offices)	92075 (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 every Interactive Data File required to be submitted 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 such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer, ” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act:

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Age.

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 October 31, 2018, the registrant had 17,427,533 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, 2018 (Unaudited)	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$6,567,918	$7,679,267
Prepaid expenses	438,957	251,046
Total current assets	7,006,875	7,930,313
Other assets	11,551	11,551
Total assets	$7,018,426	$7,941,864
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	$625,994	$1,048,927
Accrued compensation	984,683	1,025,911
Total current liabilities	1,610,677	2,074,838
Warrant liability	—	3,701,277
Total liabilities	1,610,677	5,776,115
Stockholders' equity:		
Common stock, $0.0001 par value; authorized shares - 50,000,000;		
issued and outstanding shares - 17,427,533 and 15,413,610		
at September 30, 2018 and December 31, 2017, respectively	1,743	1,541
Additional paid-in capital	82,250,109	73,202,863
Accumulated deficit	(76,844,103)	(71,038,655)
Total stockholders' equity	5,407,749	2,165,749
Total liabilities and stockholders' equity	$7,018,426	$7,941,864

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Operations

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$625,497	$2,717,698	$3,399,654	$5,505,953
General and administrative	897,060	984,047	2,846,611	3,065,595
Total operating expenses	1,522,557	3,701,745	6,246,265	8,571,548
Loss from operations	(1,522,557)	(3,701,745)	(6,246,265)	(8,571,548)
Other income (expense):				
Interest income	3,089	2,822	7,425	5,452
Change in fair value of warrant liability	—	(1,544,138)	433,392	(3,354,973)
Total other income (expense)	3,089	(1,541,316)	440,817	(3,349,521)
Net loss	$(1,519,468)	$(5,243,061)	$(5,805,448)	$(11,921,069)
Net loss per share of common stock, basic	$(0.09)	$(0.34)	$(0.36)	$(0.81)
Net loss per share of common stock, diluted	$(0.09)	$(0.34)	$(0.36)	$(0.84)
Weighted-average shares used to compute basic net loss per share	17,129,649	15,351,295	16,327,385	14,740,977
Weighted-average shares used to compute diluted net loss per share	17,129,649	15,351,295	16,327,385	14,766,853

See accompanying notes to these unaudited condensed financial statements.

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Evoke Pharma, Inc.

Condensed Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Operating activities		
Net loss	$(5,805,448)	$(11,921,069)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,161,266	1,404,926
Change in fair value of warrant liability	(433,392)	3,354,973
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(187,911)	(59,020)
Accounts payable and accrued expenses	(464,161)	1,236,986
Net cash used in operating activities	(5,729,646)	(5,983,204)
Financing activities		
Proceeds from issuance of common stock, net	4,618,297	7,389,101
Net cash provided by financing activities	4,618,297	7,389,101
Net increase (decrease) in cash and cash equivalents	(1,111,349)	1,405,897
Cash and cash equivalents at beginning of period	7,679,267	9,007,071
Cash and cash equivalents at end of period	$6,567,918	$10,412,968
Non-cash financing activities		
Reclassification of warrant liability to equity due to exercise of warrants	—	$1,399,091
Reclassification of warrant liability to equity due to amendment of warrants	$3,267,885	—

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Notes to Condensed Financial Statements

(Unaudited)

1. Organization and Basis of Presentation

Evoke Pharma, Inc. (the "Company") was incorporated in the state of Delaware in January 2007. The Company is a 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 developing its sole product, Gimoti™, and has not realized revenues from its planned principal operations. The Company filed a New Drug Application ("NDA") for Gimoti with the U.S. Food and Drug Administration ("FDA") on June 1, 2018, which was accepted and is being reviewed by FDA. However, the Company does not anticipate realizing revenues until FDA approves the NDA and the Company begins commercializing Gimoti, which events may never occur. 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.

Going Concern

The Company has incurred recurring losses and negative cash flows from operations since inception and expects to continue to incur net losses for the foreseeable future until such time, if ever, that it can generate significant revenues from the sale of Gimoti. Although the Company ended the third quarter of 2018 with approximately $6.6 million in cash and cash equivalents, the Company anticipates that it will continue to incur losses from operations due to pre-approval and pre-commercialization activities, including interactions with FDA on the Company's NDA submission for Gimoti, marketing and manufacturing of Gimoti, and general and administrative costs to support operations. As a result, the Company believes that there is substantial doubt about its ability to continue as a going concern for one year after the date these financial statements are issued.

The determination as to whether the Company can continue as a going concern contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. In its report on the Company's financial statements for the year ended December 31, 2017, 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.

The Company's net losses may fluctuate significantly from quarter to quarter and year to year. The Company believes that its current cash and cash equivalents as of September 30, 2018 will be sufficient to meet estimated working capital requirements and fund operations through June 2019. The Company will need to raise additional cash through debt, equity or other forms of financing, such as potential collaboration arrangements, to fund future operations. There can be no assurance that additional financing will be available when needed 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.

2. Summary of Significant Accounting Policies

The accompanying condensed balance sheet as of December 31, 2017, 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, 2017, which are contained in the Company's Annual Report on Form 10-K filed with the SEC on March 7, 2018. The results for interim periods are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

Use of Estimates

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

Contract Research Organizations

The Company relies on contract research organizations ("CROs") and consultants to assist with ongoing regulatory discussions and submissions supporting the NDA. If these CROs and consultants are unable to continue their support, this could adversely affect FDA's review of the NDA.

In addition, the Company relies on third-party manufacturers for the production of Gimoti. If the third-party manufacturers are unable to continue manufacturing, or if the Company loses one of its sole source suppliers used in its manufacturing processes, the Company may not be able to meet any development needs or commercial supply demand for Gimoti, if approved by FDA, and the development and/or commercialization of Gimoti could be materially and adversely affected.

Warrant Accounting

In March 2018, the Company entered into warrant amendments (the "Warrant Amendments") with each of the holders of the Company's outstanding warrants to purchase common stock issued on July 25, 2016 and August 3, 2016 (the "Warrants"). As a result of the Warrant Amendments, the Warrants will no longer be classified as a liability on the Company's balance sheet, were adjusted to fair value as of the date of the Warrant Amendments, and reclassified to additional paid-in capital, a component of stockholders' equity.

Prior to the Warrant Amendments, the Warrants were classified as warrant liability and recorded at fair value. These Warrants contained a feature that could have required the transfer of cash in the event a change of control occurred without the authorization of our board of directors, and therefore, were classified as a liability in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity.

The fair value of each warrant was estimated on the date of issuance, and each subsequent balance sheet date, using the Black-Scholes valuation model using the appropriate risk-free interest rate, expected term and volatility assumptions. The expected life of the warrant was calculated using the remaining life of the warrant. Due to the Company's limited historical data as a public company, the estimated volatility was calculated based upon the Company's historical volatility, supplemented, as necessary, with historical volatility of comparable companies in the biotechnology industry whose share prices are publicly available for a sufficient period of time. The risk-free rate was based upon U.S. Treasury securities with remaining terms similar to the expected term of the stock award being valued.

This warrant liability was subject to remeasurement at each reporting date and the Company recognized any change in the fair value of the warrant liability in the statement of operations. The Company continued to adjust the carrying value of the warrants for changes in the estimated fair value until the date of the Warrant Amendments.

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 and, if necessary, 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 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 pre-commercial product development. The Company has agreements with Cosma S.p.A. to supply metoclopramide for the manufacture of Gimoti, and with Thermo Fisher Scientific Inc., who acquired Patheon UK Limited, for product development and manufacturing of Gimoti. The Company currently utilizes third-party consultants, which it engages on an as-needed, hourly basis, to manage product development and manufacturing contractors.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common stock outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted-average number of common stock outstanding that are subject to repurchase. The Company excluded 45,000 shares of common stock subject to repurchase from the weighted-average number of common stock outstanding for the three and nine months ended September 30, 2017. Since June 2018 when the Company's repurchase right lapsed upon the filing of the NDA, the Company no longer has any common stock subject to repurchase. As such, to account for the time the common stock was subject to repurchase, the Company excluded 0 and 25,055 weighted-average shares from the weighted-average number of common stock outstanding for the three and nine months ended September 30, 2018, respectively. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of common stock subject to repurchase, warrants to purchase common stock, options to purchase common stock under the Company's equity incentive plans and potential shares to be purchased under the ESPP. For the periods presented, the following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because their inclusion would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Common stock subject to repurchase	—	45,000	25,055	45,000
Warrants to purchase common stock	2,713,561	2,797,561	2,713,561	2,771,685
Common stock options	3,017,624	2,131,624	3,017,624	2,131,624
Employee stock purchase plan	2,697	7,064	2,697	7,064
Total excluded securities	5,733,882	4,981,249	5,758,937	4,955,373

The following table sets forth the calculation of basic and diluted net loss per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss attributable to common shareholders for	$(1,519,468)	$(5,243,061)	$(5,805,448)	$(11,921,069)

basic net loss per share				
Adjustment for loss from change in fair value of warrants	—	—	—	(429,702)
Net loss used for diluted net loss per share	$(1,519,468)	$(5,243,061)	$(5,805,448)	$(12,350,771)
Weighted-average shares used to compute basic net loss per share	17,129,649	15,351,295	16,327,385	14,740,977
Adjustment to reflect assumed exercise of warrants	—	—	—	25,876
Weighted-average shares used to compute diluted net loss per share	17,129,649	15,351,295	16,327,385	14,766,853
Net loss per share attributable to common shareholders:				
Basic	$(0.09)	$(0.34)	$(0.36)	$(0.81)
Diluted	$(0.09)	$(0.34)	$(0.36)	$(0.84)

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("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. In July 2018, the FASB issued ASU No. 2018-11, Leases – Targeted Improvements to provide entities with relief from the costs of implementing certain aspects of ASU No. 2016-02. Specifically, under the amendments in ASU No. 2018-11, entities may (1) elect not to recast the comparative periods presented when transitioning to the new leasing standard, and (2) lessors may elect not to separate lease and non-lease components when certain conditions are met. ASU No. 2018-11 has the same effective date as ASU No. 2016-02. The Company's only significant lease is its facility lease, which expires on December 31, 2019. The Company does not expect the pending adoption of the new standard to have a material impact on the Company's financial statements.

3. 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 previously made to Questcor, the Company may also be required to make additional milestone payments totaling up to $52 million. In March 2018, the Company and Mallinckrodt amended the Asset Purchase Agreement to defer development and approval milestone payments, such that, rather than paying two milestone payments based on FDA acceptance for review of the NDA and final product marketing approval, the Company would be required to make a single $5 million payment one year after the Company receives FDA approval to market 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 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.

4. Stockholders' Equity

Warrants

In February 2017, an institutional investor from the Company's financing which closed in July 2016 converted its warrant to purchase 526,315 shares of the Company's common stock by a "cashless" exercise and received 211,860 shares of the Company's common stock. The warrant had an exercise price of $2.41 per share. The shares were issued, and the warrants were sold, in reliance upon the registration exemption set forth in Section 4(a)(2) of the Securities Act of 1933, as amended. The value of the exercised warrants was adjusted to the fair value immediately prior to the exercise and approximately $1.4 million was reclassified from warrant liability to additional paid-in capital, a component of stockholders' equity.

In March 2018, the Company entered into the Warrant Amendments with each of the holders of the Company's outstanding Warrants. As a result of the Warrant Amendments, all of the remaining Warrants to purchase 2,449,129 shares of the Company's common stock are no longer required to be classified as liabilities. The value of the amended Warrants was adjusted to the fair value immediately prior to the Warrant Amendments, resulting in a gain of approximately $433,000 in the statement of operations, and approximately $3.3 million was reclassified from warrant liability to additional paid-in capital.

In September 2018, warrants to purchase 84,000 shares of the Company's common stock, issued to representatives of the underwriters in connection with the Company's initial public offering in September 2013, expired and have been cancelled.

Sale of Common Stock in Public Offering

In February and March 2017, the Company completed the sale of 2,775,861 shares of its common stock in an underwritten public offering. The price to the public in this offering was $2.90 per share resulting in gross proceeds to the Company of approximately $8.0 million. After deducting underwriting discounts and commissions and offering expenses paid by the Company, the net proceeds to the Company from this offering was approximately $7.3 million.

At the Market Equity Offering Program

In November 2017, the Company filed a new shelf registration with the SEC on Form S-3 to replace a prior Form S-3 shelf registration which was set to expire on November 25, 2017. This new shelf registration was declared effective by the SEC on December 28, 2017. The new shelf registration statement includes a prospectus for the at-the-market offering to sell up to an aggregate of $16.0 million of shares of the Company's common stock through B. Riley FBR, Inc. ("FBR") as a sales agent (the "FBR Sales Agreement"). The Company did not sell any shares of common stock through the FBR Sales Agreement during 2017. During the nine months ended September 30, 2018, the Company sold 1,985,054 shares of common stock at a weighted-average price per share of $2.38 pursuant to the FBR Sales Agreement and received proceeds of approximately $4.6 million, net of commissions and fees. From October 1, 2018 through October 31, 2018, the Company has not sold any additional shares of common stock pursuant to the FBR Sales Agreement.

Under current SEC regulations, if at the time the Company files its Annual Report on Form 10-K ("Form 10-K"), and the Company's public float is less than $75 million, and for so long as its public float remains less than $75 million, the amount the Company can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of the Company's public float, which is referred to as the baby shelf rules. As of October 31, 2018, the Company's public float was approximately $47.8 million, based on 14,349,303 shares of outstanding common stock held by non-affiliates and at a price of $3.33 per share, which was the last reported sale price of the Company's common stock on the Nasdaq Capital Market on September 17, 2018. As a result of the Company's public float being below $75 million, the Company will be limited by the baby shelf rules until such time as the Company's public float exceeds $75 million, which means the Company only has the capacity to sell shares up to one-third of its public float under shelf registration statements in any twelve-month period. If the Company's public float decreases, the amount of securities the Company may sell under its Form S-3 shelf registration statement will also decrease. As of October 31, 2018, the Company had the capacity to issue up to approximately $11.2 million worth of additional shares of common stock pursuant to the FBR Sales Agreement.

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. 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. 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 $47,000 and $135,000, the Company sold 28,869 and 75,529 shares of common stock through its ESPP during the nine months ended September 30, 2018 and 2017, respectively.

In May 2017, the Company's stockholders approved an amendment and restatement of the Company's ESPP to increase the number of shares of common stock reserved under the ESPP by 100,000 shares (to an aggregate of 1,250,000 shares), to increase the annual evergreen provision from 30,000 shares to 100,000 shares, and to extend the term of the ESPP into 2027.

On April 26, 2018, the Company's stockholders approved the amendment and restatement of the Company's 2013 Equity Incentive Award Plan (the "Restated Equity Incentive Plan") to increase the number of shares of common stock authorized for issuance under the Restated Equity Incentive Plan by 1,500,000 shares, to an aggregate of 6,286,425 shares, and to extend the term of the Restated Equity Incentive Plan to February 2028. In addition, beginning on January 1, 2019, the number of shares available for issuance will be annually increased on the first day of each fiscal year by that number of shares equal to the least of (a) four percent of the outstanding shares of common stock on the last day of the immediately preceding calendar year, and (b) such other amount determined by the Company's board of directors. Notwithstanding the foregoing, the number of shares of common stock that may be issued or transferred pursuant to incentive stock options under the Restated Equity Incentive Plan may not exceed an aggregate of 8,000,000 shares.

Stock-Based Compensation

Stock-based compensation expense includes charges related to employee stock purchases under the ESPP and stock option grants. 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 nine months ended September 30, 2018 and 2017:

	Nine Months Ended	
	September 30,	
	2018	2017
Common Stock Options		
Risk free interest rate	2.66% - 2.85%	1.93% - 2.16%
Expected option term	5.5 - 6.0 years	5.5 - 6.0 years
Expected volatility of common stock	90.15% - 92.30%	94.05% - 98.25%
Expected dividend yield	0.0%	0.0%

There were no stock options granted during the three months ended September 30, 2018 and 2017.

The estimated fair value of the shares to be acquired under the ESPP was determined on the initiation date of each six-month purchase period using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for ESPP shares to be purchased during the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Employee Stock Purchase Plan				
Risk free interest rate	2.29%	1.10%	1.85% - 2.29%	0.79% - 1.10%
Expected term	6 months	6 months	6 months	6 months
Expected volatility of common stock	45.24%	37.60%	45.24% -	37.60% -

			58.76%	99.23%
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		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Research and development	$161,515	$200,773	$519,025	$626,976
General and administrative	218,547	275,124	642,241	777,950
Total stock-based compensation expense	$380,062	$475,897	$1,161,266	$1,404,926

As of September 30, 2018, 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 1.24 years.

5. 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 third quarter of 2016 the Company entered into an agreement 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.

As noted in Notes 2 and 4, due to the Warrant Amendments in March 2018, the warrant liability was reclassified to additional paid-in capital. Prior to the Warrant Amendments, the Company utilized a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritized 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, prior to the Warrant Amendments of the warrants, were classified as Level 3.

The Company classified the warrants as a liability and remeasured the liability to the estimated fair value at December 31, 2017 using the Black Scholes option pricing model with the following assumptions:

	December 31, 2017
Risk-free interest rate	2.09%
Expected volatility	100.39%
Expected term	4.08 years
Expected dividend yield	0.0%

The following table presents a reconciliation of the Company's warrant liability measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the nine months ended September 30, 2018 and 2017:

	September 30,	
	2018	2017
Beginning balance of warrant liability	$3,701,277	$4,095,019
Change in fair value upon re-measurement	(433,392)	3,354,973
Reclassification to Additional Paid-in Capital due to warrant exercise	—	(1,399,091)
Reclassification to Additional Paid-in Capital due to warrant amendment	(3,267,885)	—
Ending balance of warrant liability	$-	$6,050,901

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, 2017 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 7, 2018. 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, "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. As a result of many factors, including without limitation those set forth under "Risk Factors" under Item 1A of Part II below, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. Except as required by applicable law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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, or GI, disorders and diseases. We are developing Gimoti, an investigational metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. Diabetic gastroparesis is a GI disorder afflicting millions of people worldwide and is characterized by slow or delayed gastric emptying and

evidence of gastric retention in the absence of mechanical obstruction and can cause various serious digestive system symptoms and other complications. Metoclopramide tablets and injection are the only products currently approved in the United States to treat the symptoms associated with acute and recurrent diabetic gastroparesis. Gimoti is a novel nasal spray formulation of metoclopramide and designed to provide systemic delivery of the molecule through the nasal mucosa. We submitted a New Drug Application, or NDA, for Gimoti to the U.S. Food and Drug Administration, or FDA, on June 1, 2018 and received our Day-74 FDA filing communication letter in August 2018. The letter stated that our NDA was sufficiently complete to permit a substantive review and set a target goal date under the Prescription Drug User Fee Act, or PDUFA, of April 1, 2019.

In July 2016, we announced results from a Phase 3 clinical trial of Gimoti in female subjects with symptoms associated with acute and recurrent diabetic gastroparesis. The trial was a multicenter, randomized, double-blind, placebo-controlled, parallel group clinical trial to evaluate the efficacy, safety and population pharmacokinetics, or PK, of 10 mg Gimoti in adult female subjects with symptomatic diabetic gastroparesis and delayed gastric emptying scintigraphy, or GES. Subjects received either Gimoti or placebo four times daily for 28 days. 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. On a daily basis, subjects reported the frequency and severity of their gastroparesis signs and symptoms using a telephone diary. The subjects' daily symptom scores were the basis for calculating their weekly scores

using the PRO instrument. A total of 205 subjects were randomized in this trial. Results of the trial showed that Gimoti did not achieve its primary endpoint of a symptom improvement at Week 4 in the intent to treat, or ITT, population.

Although the Phase 3 trial failed to achieve its primary endpoint, Gimoti demonstrated efficacy in patients with moderate to severe symptoms at baseline, which included 105 of the 205 patients (51%) enrolled in the study. In these patients with higher symptom severity, statistically significant benefits were demonstrated for those treated with Gimoti versus those receiving placebo. These statistically significant benefits were observed at Weeks 1, 2 and 3 in the ITT population and at all four weeks in the per protocol population. There were also clinically and statistically significant improvements in nausea and upper abdominal pain, two of the more severe and debilitating symptoms of gastroparesis, at all four weeks.

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 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 new drug application, or NDA, for women; however, we included safety data from this trial in the NDA submission. As we anticipated at the beginning of the trial, based on the prior Phase 2b data, the results of the trial showed no statistical significant efficacy in men and the safety profile for Gimoti was favorable compared to placebo with good tolerability.

In December 2016, we had a pre-NDA meeting with FDA, in which FDA agreed that a comparative exposure PK trial was acceptable as a basis for submission of a Gimoti NDA. In March 2017, we had a type A meeting with FDA to finalize the design of the comparative exposure PK trial and reach agreement on certain other chemistry, manufacturing and controls-related items associated with the proposed NDA submission.

In October 2017, we announced positive topline results from the comparative exposure PK trial. The objective of the trial was to identify a dose of Gimoti that met the criteria for bioequivalence compared to the Reglan Tablets after nasal and oral administration to healthy volunteers under fasted conditions.

The comparative exposure PK trial was an open label, 4-way crossover and enrolled 108 healthy male and female volunteers who each received one Reglan Tablet dose and three different doses of Gimoti in a random sequence. Following discussions at pre-NDA meetings with FDA, we planned to select a Gimoti dose based on criteria that includes a 90% confidence interval for the ratio of area under the plasma concentration curve, or AUC, falling within the exposure equivalence range of 80-125% of Reglan Tablets. Though only one dose was needed to meet the dose selection criteria, the comparative exposure PK trial was designed to test three different strengths of Gimoti. Based on results of the study, two of the three doses tested met the dose selection criteria for the pooled data in women and men. The maximum observed plasma concentration, or C_{max}, for Gimoti was slightly lower than the equivalence range, as was anticipated and had been previously discussed with FDA as a likely outcome given the different route of administration and prior Gimoti PK trial results. Additionally, data showed the AUC and C_{max} increased in a dose related manner across all three strengths tested. Relative to safety, all Gimoti doses were well tolerated with no clinically significant adverse events reported following any of the doses.

Additional analysis of the PK data by sex revealed statistically significant differences in exposure between women and men given the same metoclopramide dose (nasal and oral). Based on this further analysis of results from the comparative exposure PK trial, statistically significantly lower AUC's were found in men compared to women. The findings were not explicitly attributable to differences in body mass index, or BMI, or weight. Similarly, sex-based differences were observed in a previous healthy volunteer study we conducted, irrespective of the route of metoclopramide administration (nasal, oral and IV).

In the most recent comparative exposure PK trial, results for women independently met equivalence criteria for $AUC_{0\text{-}inf}$ and $AUC_{0\text{-}t}$ at the tested Gimoti dose to be proposed in the NDA. We submitted our NDA for a female-only indication based on a dose in women with equivalent exposure to Reglan Tablets and submitted supporting efficacy and safety data from our Phase 2b and Phase 3 trials, specifically for women, at doses similar or lower than the dose to be proposed in the NDA.

In addition, we held a pre-NDA meeting with FDA to discuss and clarify its expectations of items being prepared for inclusion in the NDA for Gimoti. The NDA included our proposal for a risk management strategy and a post-approval safety study that will be designed to confirm prior safety findings and rule-out possible differences in side effects compared to the Reglan Tablet over 8 weeks. We expect to discuss the details of the post-marketing safety trial with FDA during the NDA review process.

In March 2018, we announced that FDA granted our request for a small business waiver of the PDUFA fee of approximately $2.4 million for its 505(b)(2) NDA for Gimoti.

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 prior to our initial public offering in September 2013, borrowings under our bank loans 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 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, 2018, we had cash and cash equivalents of approximately $6.6 million. We believe our existing cash and cash equivalents as of September 30, 2018 will be sufficient to fund our operations through June 2019. Current funds on hand are intended to fund a portion of the pre-approval and pre-commercialization activities for Gimoti, including interactions with FDA on our NDA submission for Gimoti, marketing and manufacturing of Gimoti, and general and administrative costs to support operations.

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 previously made to Questcor, we may be required to make additional milestone payments totaling up to $52 million. In March 2018, we amended the asset purchase agreement with Mallinckrodt to defer development and approval milestone payments, such that rather than paying two milestone payments based on FDA acceptance for review of the NDA and final product marketing approval, we would be required to make a single $5 million payment one year after we receive FDA approval to market 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 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.

Financial Operations Overview

Research and Development Expenses

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

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

All of our research and development expenses to date have been incurred in connection with the development of Gimoti. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. While we submitted our NDA for Gimoti in June 2018, the successful development and commercialization of Gimoti is still highly uncertain. We are unable to estimate with any certainty the costs we will

incur in the continued development and regulatory review of Gimoti, though such costs may be significant. 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 increase in the future as we expand our operating activities, prepare for the growth needs associated with potential commercialization of Gimoti and continue to incur additional costs associated with being a publicly-traded company and maintaining compliance with exchange listing and SEC requirements. These increases will likely include higher consulting costs, legal fees, accounting fees, directors' and officers' liability insurance premiums and fees associated with investor relations.

Other Income (Expense)

Other income (expense), net consists primarily 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 was revalued each reporting period until March 2018, when we entered into warrant amendments, or the Warrant Amendments, with each of the holders of the Company's outstanding warrants to purchase common stock issued on July 25, 2016 and August 3, 2016, or the Warrants. We previously used the Black Scholes valuation model to value the related warrant liability at each reporting date. As a result of the Warrant Amendments, the Warrants will no longer be required to be accounted for as a liability and will no longer be required to be revalued at each reporting period.

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, 2017, which was filed with the SEC on March 7, 2018.

Other Information

Tax Cuts and Jobs Act

In December 2017, tax legislation commonly known as the Tax Cuts and Jobs Act, or the Act, was signed into law. The effects of the new federal legislation were recognized upon enactment, which was the date the bill was signed into law. The Act includes numerous changes in existing tax law, including a permanent reduction in the federal corporate income tax rate from 35% to 21%. The rate reduction took effect on January 1, 2018. As a result of this rate change, we have revalued our deferred tax assets at December 31, 2017. Deferred income taxes result from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements that will result in taxable or deductible amounts in future years. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in years in which those temporary differences are expected to be recovered or settled. As changes in tax laws or rates are enacted, deferred tax assets and liabilities are adjusted through income tax expense. We recorded a reduction of approximately $7.9 million in the fourth quarter of 2017 related to the revaluation of our deferred

tax assets, which did not result in additional tax expense in the quarter as our deferred tax assets have a full valuation allowance. This amount may be subject to further adjustment in subsequent periods throughout 2018 in accordance with subsequent interpretive guidance issued by the SEC or the Internal Revenue Service. Further, there may be other material adverse effects resulting from the legislation that we have not yet identified.

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 $1.07 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. Unless we lose our status as an emerging growth company earlier, we will cease being an emerging growth company on December 31, 2018.

Results of Operations

Comparison of Three Months Ended September 30, 2018 and 2017

The following table summarizes the results of our operations for the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Increase/ (Decrease)
	2018	2017	
Research and development expenses	$625,497	$2,717,698	$(2,092,201)
General and administrative expenses	$897,060	$984,047	$(86,987)
Other (income) expense	$(3,089)	$1,541,316	$(1,544,405)

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2018 compared to the three months ended September 30, 2017 decreased by approximately $2.1 million due primarily to our comparative exposure PK trial being conducted during the third quarter of 2017, while in 2018 we incurred time and resource expenses primarily related to responding to questions from FDA for the Gimoti NDA. Costs incurred in 2018 included approximately $566,000 for wages, taxes and employee insurance, including approximately $162,000 of stock-based compensation expense. Costs incurred in 2017 included approximately $1.8 million of

clinical trial costs, approximately $601,000 for wages, taxes and employee insurance, including approximately $201,000 of stock-based compensation expense, and approximately $337,000 of costs related to the preparation of the NDA.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2018 compared to the three months ended September 30, 2017 decreased by approximately $87,000. Costs incurred in 2018 primarily included approximately $502,000 for wages, taxes and employee insurance, including approximately $219,000 of stock-based compensation expense, and approximately $299,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. Costs incurred in 2017 primarily included approximately $542,000 for wages, taxes and employee insurance, including approximately $275,000 of stock-based compensation expense, and approximately $309,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

Other (Income) Expense. Other (income) expense for the three months ended September 30, 2018 compared to the three months ended September 30, 2017 decreased by approximately $1.5 million due primarily to the revaluation of Warrants no longer being required since the date of the Warrant Amendment in March 2018. Prior to the amendment, the Warrants were accounted for as a liability and were required to be revalued at each reporting period.

Comparison of Nine Months Ended September 30, 2018 and 2017

The following table summarizes the results of our operations for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		Increase/ (Decrease)
	2018	2017	
Research and development expenses	$3,399,654	$5,505,953	$(2,106,299)
General and administrative expenses	$2,846,611	$3,065,595	$(218,984)
Other income (expense)	$(440,817)	$3,349,521	$(3,790,338)

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 decreased by approximately $2.1 million. During the first nine months of 2018 we were preparing our NDA for filing with FDA, while during the first nine months of 2017 we were preparing for and conducting our comparative exposure PK trial, including manufacturing Gimoti for such trial. Costs incurred in 2018 include approximately $1.9 million for wages, taxes and employee insurance, including approximately $519,000 of stock-based compensation expense, approximately $1.2 million of NDA preparation costs, and approximately $329,000 related to manufacturing costs. Costs incurred in 2017 include approximately $2.1 million for clinical trial costs, approximately $1.9 million for wages, taxes and employee insurance, including approximately $627,000 of stock-based compensation expense, approximately $958,000 related to manufacturing costs, and approximately $561,000 related to the preparation of the NDA.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 decreased by approximately $219,000. Costs incurred in 2018 primarily included approximately $1.4 million for wages, taxes and employee insurance, including approximately $642,000 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 2017 primarily included approximately $1.6 million for wages, taxes and employee insurance, including approximately $778,000 of stock-based compensation expense, and approximately $1.2 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

Other (Income) Expense. Other (income) expense for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 decreased by approximately $3.8 million due primarily to the revaluation of Warrants no longer being required since the date of the Warrant Amendment in March 2018. Prior to the amendment, the Warrants were accounted for as a liability and were required to be revalued at each reporting period.

Liquidity and Capital Resources

In November 2017, we filed a new shelf registration with the SEC on Form S-3 to replace a prior Form S-3 shelf registration which was set to expire on November 25, 2017. This new shelf registration was declared effective by the SEC on December 28, 2017. The new shelf registration statement includes a prospectus for the at-the-market offering to sell up to an aggregate of $16.0 million of shares of the Company’s common stock through B. Riley FBR, Inc., or FBR, as a sales agent, or the FBR Sales Agreement. We did not sell any shares of common stock through the FBR Sales Agreement during 2017. Through September 30, 2018, the Company sold 1,985,054 shares of common stock at a weighted-average price per share of $2.38 pursuant to the FBR Sales Agreement and received proceeds of approximately $4.6 million, net of commissions and fees. From October 1, 2018 through October 31, 2018, we have

not sold any additional shares of common stock pursuant to the FBR Sales Agreement.

Under current SEC regulations, if at the time we file our Annual Report on Form 10-K, or Form 10-K, our public float is less than $75 million, and for so long as our public float remains less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float, which is referred to as the baby shelf rules. As of October 31, 2018, our public float was approximately $47.8 million, based on 14,349,303 shares of outstanding common stock held by non-affiliates and at a price of $3.33 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on September 17, 2018. As a result of our public float being below $75 million, we will be limited by the baby shelf rules until such time as our public float exceeds $75 million, which means we only have the capacity to sell shares up to one-third of our public float under shelf registration statements in any twelve-month period. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease. As of October 31, 2018, we had the capacity to issue up to approximately $11.2 million worth of additional shares of common stock pursuant to 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. 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.

In addition, we 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 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.

In February 2017, an institutional investor from our financing which closed in July 2016 converted its warrant to purchase 526,315 shares of our common stock by a "cashless" exercise and received 211,860 shares of our common stock. The warrant had an exercise price of $2.41 per share. The shares were issued, and the warrants were sold, in reliance upon the registration exemption set forth in Section 4(a)(2) of the Securities Act of 1933, as amended. The value of the exercised warrants was adjusted to the fair value immediately prior to the exercise and approximately $1.4 million was reclassified from warrant liability to Additional Paid-in Capital.

In February and March 2017, we completed the sale of 2,775,861 shares of our common stock in an underwritten public offering. The price to the public in this offering was $2.90 per share resulting in gross proceeds to us of approximately $8.0 million. After deducting underwriting discounts and commissions and offering expenses paid by us, the net proceeds to us from this offering was approximately $7.3 million.

In March 2018, we entered into the Warrant Amendments with each of the holders of our outstanding Warrants. As a result of the Warrant Amendments, all of the remaining Warrants to purchase 2,449,129 shares of our common stock are no longer required to be classified as liabilities. The value of the amended Warrants was adjusted to the fair value immediately prior to the Warrant Amendments, resulting in a gain of approximately $433,000 in the statement of operations, and approximately $3.3 million was reclassified from warrant liability to additional paid-in capital, a component of stockholders' equity.

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, 2017 with respect to our ability to continue as a going concern. This doubt about our ability to continue as a going concern 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 Gimoti, 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 June 2019. This period could be shortened if there are any significant increases in planned spending on our pre-approval and pre-commercialization activities, including interactions with FDA on our NDA submission for Gimoti, marketing and manufacturing of Gimoti, and our general and administrative costs to support operations. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

We 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 the pre-approval and pre-commercialization activities for Gimoti;
- prepare for and complete further clinical development, if necessary;
- 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 June 2019, it may not be sufficient to complete any additional development requirements requested by FDA or to commercialize Gimoti. 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 described below, including the costs associated with FDA review of the Gimoti NDA and the extent of any additional clinical development required by FDA. We anticipate that we will seek to fund our operations through public or private

equity, debt financings or other sources, such as potential collaboration arrangements. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies.

The following table summarizes our cash flows for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,	
	2018	2017
Net cash used in operating activities	$(5,729,646)	$(5,983,204)
Net cash provided by financing activities	$4,618,297	$7,389,101
Net increase (decrease) in cash and cash equivalents	$(1,111,349)	$1,405,897

Operating Activities. The primary use of our cash has been to fund our clinical research and other general operations. The cash used in operating activities during the nine months ended September 30, 2018 was primarily related to the preparation of our NDA. The cash used in operating activities during the nine months ended September 30, 2017 was primarily related to preparing for our comparative exposure PK clinical trial and the manufacturing of Gimoti for such trial. We expect that cash used in operating activities for the remainder of 2018 will remain consistent with the three months ended September 30, 2018.

Financing Activities. During the nine months ended September 30, 2018, we received net proceeds of approximately $4.6 million from the sale of 1,985,054 shares of common stock pursuant to the FBR Sales Agreement. During the nine months ended September 30, 2017, we received net proceeds of approximately $7.3 million from the sale of 2,775,861 shares of common stock from an underwritten public offering. In addition, during the nine months ended September 30, 2018 and 2017, we received proceeds of approximately $47,000 and $135,000 from the sale of 28,869 and 75,529 shares of common stock, respectively, through our ESPP.

We believe that our existing cash and cash equivalents as of September 30, 2018 will be sufficient to meet our anticipated cash requirements and fund operations through June 2019. 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:

- 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;
- we may be required to undertake additional clinical trials and other studies of Gimoti before we receive approval of the NDA;
- 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;
- 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 or other bioequivalence parameters required by FDA for marketing approval;
- 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 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 establish commercial-scale manufacturing capabilities.

Off-Balance Sheet Arrangements

Through September 30, 2018, 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

There were no material changes outside the ordinary course of our business during the nine months ended September 30, 2018 to the information regarding our contractual obligations that was disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

As of September 30, 2018, 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, 2017.

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, 2018.

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, 2017, other than as set forth below:

Our business is entirely dependent on the success of Gimoti, which 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 pursue regulatory approval based on the results of our completed comparative exposure PK trial, 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. In July 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 in the Intent-to-Treat (ITT) group at Week 4.

In December 2016, we announced the completion of a pre-NDA meeting with FDA, in which FDA agreed that a comparative exposure PK trial was acceptable as a basis for submission of a Gimoti NDA. Data from the comparative exposure PK trial will serve as a portion of the 505(b)(2) data package to include prior efficacy and safety data developed by us and FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets. In October 2017, we announced positive topline results from the comparative exposure PK trial. In addition, based on feedback received from FDA at an additional pre-NDA meeting, we proposed a risk mitigation strategy and post-approval safety trial as part of our NDA submission. We submitted the NDA for Gimoti to FDA on June 1, 2018 and received our Day-74 communication letter in August 2018. The letter stated that our NDA was sufficiently complete to permit a substantive review and set a target goal date under PDUFA of April 1, 2019. Even with the issuance of the Day-74 letter, FDA may raise substantive filing review issues, such as the potential review issues identified by FDA in the Day-74 letter, including, among others, C_{max} falling below the bioequivalence range in the comparative exposure PK trial, the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced listed drug, Reglan Tablets, and the available safety database supporting such duration, the adequacy of the proposed risk evaluation and mitigation strategy, or REMS, included in the NDA, and the existing data supporting a female-only indication.

Because our business is entirely dependent on the success of Gimoti, if we are unable to successfully complete development of and receive regulatory approval of 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, including as a result of the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced Listed Drug, Reglan Tablets;

- FDA may disagree with the design of any other future clinical trials, if any are necessary;
- variability in subjects, adjustments to clinical trial procedures and inclusion of additional clinical trial sites;
- FDA may not agree with the analysis of our clinical trial results, including our analysis of results of the PK trial;
- the results of our clinical trials may not meet the level of statistical or clinical significance or other bioequivalence parameters required by FDA for marketing approval, including C_{max} falling below the equivalence range in the comparative exposure PK trial;
- we may be required to undertake additional clinical trials and other studies of Gimoti before we can submit an NDA to 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 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 maintain commercial manufacturing arrangements with third-party manufacturers or establish and maintain 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 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 June 2019, 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 beyond that time.

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 need for, and the progress, costs and results of, any additional clinical trials of Gimoti that may be required by FDA, including any pre-approval or post-approval trials FDA or other regulatory agencies may require evaluating the efficacy or safety of Gimoti;
- the costs involved for additional data collection and analysis to respond to FDA questions related to the NDA;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from FDA, and any similar regulatory agencies;
- the costs and timing of completion of outsourced commercial manufacturing supply arrangements for Gimoti;
- the costs of establishing or outsourcing sales, marketing and distribution capabilities;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Gimoti;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; 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. If we raise additional funds by incurring debt, the terms of the debt may involve significant cash payment obligations, as well as covenants and specific financial ratios that may restrict our ability to operate our business. 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.

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

We have submitted an NDA, but have not received regulatory approval to market any product candidates in any jurisdiction. We are not permitted to market Gimoti in the United States until we receive approval of an NDA for Gimoti in a particular indication from FDA. To date, we have completed a Phase 1 bioavailability and pharmacokinetics trial, a comparative exposure PK trial, a Phase 3 clinical trial in female subjects, a Phase 3 clinical trial in male subjects, a Thorough ECG (QT/QTc) study, a Phase 2b clinical trial and we acquired the results from a separate Phase 2 clinical trial in diabetic subjects with gastroparesis. In the Phase 2b clinical trial that we performed ourselves, which concluded in 2011, Gimoti failed to meet the primary endpoint for the trial. Although an overall improvement in symptoms was observed in Gimoti-treated subjects with diabetic gastroparesis compared to placebo in this Phase 2b

clinical trial, the difference was not statistically significant due to a high placebo response among male subjects. The earlier Phase 2 clinical trial performed by Questcor was a multicenter, randomized, open-label, parallel design study. This head-to-head study compared the efficacy and safety of two doses of metoclopramide nasal spray, 10 mg and 20 mg, with FDA-approved 10 mg metoclopramide tablet. Although data from the earlier Phase 2 clinical trial was referenced in the Gimoti NDA, the open-label study design limits the importance of the efficacy results in the NDA.

We completed our Phase 3 clinical trial in female subjects with symptoms associated with acute and recurrent diabetic gastroparesis and announced in July 2016 that Gimoti did not achieve its primary endpoint of symptom improvement at Week 4. While we submitted the results from the comparative exposure PK trial as a portion of the 505(b)(2) NDA submission that will include prior efficacy and safety data developed by us along with FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets, there is no guarantee that regulators will agree with our assessment of the clinical trials for Gimoti conducted to date, including the comparative exposure PK trial. In addition, we have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third-party contract research organizations to assist us in this process. FDA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional clinical trials, or preclinical or other studies.

Varying interpretation of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, we have acquired our rights to Gimoti from Questcor, who acquired its rights from a predecessor. Thus, much of the preclinical and a portion of the clinical data relating to Gimoti that we submitted in the NDA for Gimoti was obtained from studies conducted before we owned the rights to the product candidate and, accordingly, was prepared and managed by others. These predecessors may not have applied the same resources and given the same attention to this development program as we would have if we had been in control from inception.

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

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

We submitted an NDA for Gimoti in June 2018. Under PDUFA, FDA is subject to a two-tiered system of review times – Standard Review and Priority Review. For drugs subject to standard review, such as Gimoti, FDA has a goal to complete its review of the NDA and respond to the applicant within ten months from the date of receipt of an NDA. In its Day-74 filing communication letter, FDA assigned a target goal date of April 1, 2019 for the Gimoti NDA. The review process and the PDUFA goal date may be extended if FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission prior to the PDUFA target goal date. FDA's review goals are subject to change, and it is unknown whether the review of our NDA will be completed within FDA's review goals or will be delayed. Moreover, the duration of FDA's review may depend on the number and type of other NDAs that are submitted with FDA around the same time period. In addition, FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

We cannot provide any assurance as to whether or when we will obtain regulatory approval to commercialize Gimoti. We cannot, therefore, predict the timing of any future revenue. Because Gimoti is our only product candidate this risk is particularly significant for us. We cannot commercialize Gimoti until the appropriate regulatory authorities have reviewed and approved marketing applications for this product candidate. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for Gimoti. In addition, we may experience delays or the application may be rejected based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. For example, in 2009 following an FDA review of metoclopramide spontaneous safety reports, FDA required a boxed warning be added to the metoclopramide product label concerning the chance of tardive dyskinesia, or TD, for patients taking these products. FDA requires a boxed warning (sometimes referred to as a “Black Box” Warning) for products that have shown a significant risk of severe or life-threatening adverse events. Recently, the European Medicines Agency’s Committee on Medicinal Products for Human Use, or CHMP, has reviewed and has proposed labeling changes for marketed metoclopramide products in the European Union based on age, dosing guidelines or indications. Based on their assessment of the limited efficacy and safety data currently available to the CHMP, the CHMP recommended to the European Medicines Agency that indications with limited or inconclusive efficacy data, including GERD, dyspepsia and gastroparesis, be removed from the approved product label in the European Union. There can be no assurance as to whether FDA will re-review approved metoclopramide product

labels as a result of any such regulatory actions in the European Union or otherwise. If marketing approval for Gimoti is delayed, limited or denied, our ability to market the product candidate, and our ability to generate product sales, would be adversely affected.

In addition, in a written communication, FDA responded to our request for proprietary name review by conditionally accepting our proposed proprietary brand name, Gimoti. However, FDA could still fail to finally approve this proprietary name through the NDA review process. FDA typically conducts a rigorous review of proposed product names, including an evaluation of potential for confusion with the names of other products, which could lead to identification of the wrong medication or other prescribing, ordering, dispensing, administration, or monitoring errors. FDA may also object to a product name if it believes the name functions to overstate the efficacy, minimize the risk, broaden the proposed indication, make unsubstantiated superiority claims, or is otherwise false or misleading. If FDA objects to the product name Gimoti as part of the NDA review process, we may be required to adopt an alternative name for our product candidate. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for Gimoti and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidate.

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

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

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

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements or applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of product, or request us to initiate a product recall.

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

FDA has the authority to require a REMS as a condition of approval of an NDA or following approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. In March 2009, FDA informed drug manufacturers that it will require a REMS for metoclopramide drug products, including a Medication Guide, elements to assure safe use (including an education program for prescribers and materials for prescribers to educate patients), and a timetable for submission of assessments of at least six months, 12 months, and annually after the REMS is approved. In addition, FDA requested we include a proposal for a risk mitigation strategy in our NDA submission, and we have proposed elements of a REMS and a proposal for a post-approval safety trial with the NDA submission for Gimoti. At this time the elements of the REMS for Gimoti are unclear as there are varying levels of requirements that may include a Medication Guide, similar to the Reglan Tablet, and other elements, such as a communication plan and an implementation plan, designed to ensure safe use, as well as a timetable for submission of post-marketing assessments after the REMS is approved.

In addition, if Gimoti is approved, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by FDA as reflected in the product’s approved labeling. If we receive

marketing approval for Gimoti, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current administration may impact our business and industry. Namely, several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, a hiring freeze was ordered for all executive departments and agencies, including FDA, which prohibits FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze will remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget, or OMB, in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. Although certain positions at FDA may be exempt from the freeze, an under-staffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Moreover, on January 30, 2017, an additional Executive Order was issued applicable to all executive agencies, including FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

Unregistered Sales of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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 25, 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 August 3, 2016
4.7 (6)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
4.8 (7)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
4.9 (8)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
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.
(6) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on December 16, 2016
(7) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on March 23, 2018
(8) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on April 4, 2018

* 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Evoke Pharma, Inc.

Date: November 13, 2018	By:	/s/ David A. Gonyer David A. Gonyer President and Chief Executive Officer (Principal Executive Officer)
Date: November 13, 2018	By:	/s/ Matthew J. D'Onofrio Matthew J. D'Onofrio Executive Vice President, Chief Business Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)