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Evoke Pharma Inc
Form 10-Q
November 14, 2017

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, 2017

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)

420 Stevens Avenue, Suite 370, Solana Beach, CA
(Address of principal executive offices)

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

20-8447886
(IRS Employer

Identification
No.)

92075
(Zip Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 (Do not check if a smaller reporting company) 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 Act.

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

As of November 3, 2017, the registrant had 15,413,610 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, | December 31, |
|---|---------------------|-----------------|
| | 2017 (Unaudited) | 2016 |
| Assets | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 10,412,968 | \$ 9,007,071 |
| Prepaid expenses | 334,728 | 267,711 |
| Other current assets | — | 7,997 |
| Total current assets | 10,747,696 | 9,282,779 |
| Other assets | 11,551 | 11,551 |
| Total assets | \$ 10,759,247 | \$ 9,294,330 |
| Liabilities and stockholders' equity | | |
| Current Liabilities: | | |
| Accounts payable and accrued expenses | \$ 1,720,816 | \$ 478,223 |
| Accrued compensation | 927,843 | 933,450 |
| Total current liabilities | 2,648,659 | 1,411,673 |
| Warrant liability | 6,050,901 | 4,095,019 |
| Total liabilities | 8,699,560 | 5,506,692 |
| Stockholders' equity: | | |
| Common stock, \$0.0001 par value; authorized shares - 50,000,000; | | |
| issued and outstanding shares - 15,413,610 and 12,350,360 | | |
| at September 30, 2017 and December 31, 2016, respectively | 1,541 | 1,235 |
| Additional paid-in capital | 72,788,358 | 62,595,546 |
| Accumulated deficit | (70,730,212) | (58,809,143) |
| Total stockholders' equity | 2,059,687 | 3,787,638 |
| Total liabilities and stockholders' equity | \$ 10,759,247 | \$ 9,294,330 |

See accompanying notes to these unaudited condensed financial statements.

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Evoke Pharma, Inc.

Condensed Statements of Operations

(Unaudited)

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|----------------|-------------------|----------------|
| | September 30, | | September 30, | |
| | 2017 | 2016 | 2017 | 2016 |
| Operating expenses: | | | | |
| Research and development | \$2,717,698 | \$1,339,343 | \$5,505,953 | \$5,449,568 |
| General and administrative | 984,047 | 830,092 | 3,065,595 | 2,770,500 |
| Total operating expenses | 3,701,745 | 2,169,435 | 8,571,548 | 8,220,068 |
| Loss from operations | (3,701,745) | (2,169,435) | (8,571,548) | (8,220,068) |
| Other income (expense): | | | | |
| Interest income (expense), net | 2,822 | (123,209) | 5,452 | (268,483) |
| Financing costs related to warrant liability | — | (533,692) | — | (533,692) |
| Change in fair value of warrant liability | (1,544,138) | (198,945) | (3,354,973) | (198,945) |
| Total other expense, net | (1,541,316) | (855,846) | (3,349,521) | (1,001,120) |
| Net loss | \$(5,243,061) | \$(3,025,281) | \$(11,921,069) | \$(9,221,188) |
| Net loss per share of common stock, basic | \$ (0.34) | \$ (0.29) | \$ (0.81) | \$ (1.11) |
| Net loss per share of common stock, diluted | \$ (0.34) | \$ (0.29) | \$ (0.89) | \$ (1.11) |
| Weighted-average shares used to compute basic net loss per share | 15,351,295 | 10,614,692 | 14,740,977 | 8,341,750 |
| Weighted-average shares used to compute diluted net loss per share | 15,351,295 | 10,614,692 | 14,766,853 | 8,341,750 |

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Cash Flows

(Unaudited)

| | Nine Months Ended | |
|---|-------------------|----------------|
| | September 30, | |
| | 2017 | 2016 |
| Operating activities | | |
| Net loss | \$(11,921,069) | \$(9,221,188) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 1,404,926 | 1,298,279 |
| Non-cash interest | — | 120,889 |
| Financing costs allocated to warrant liability | — | 533,692 |
| Change in fair value of warrant liability | 3,354,973 | 198,945 |
| Change in operating assets and liabilities: | | |
| Prepaid expenses and other assets | (59,020) | 408,030 |
| Accounts payable and accrued expenses | 1,236,986 | (676,745) |
| Net cash used in operating activities | (5,983,204) | (7,338,098) |
| Financing activities | | |
| Payment of bank loan | — | (4,500,000) |
| Proceeds from issuance of common stock, net | 7,389,101 | 358,023 |
| Proceeds from issuance of common stock and warrants, net | — | 13,168,802 |
| Net cash provided by financing activities | 7,389,101 | 9,026,825 |
| Net increase in cash and cash equivalents | 1,405,897 | 1,688,727 |
| Cash and cash equivalents at beginning of period | 9,007,071 | 8,691,155 |
| Cash and cash equivalents at end of period | \$10,412,968 | \$10,379,882 |
| Supplemental disclosure of cash flow information | | |
| Interest paid | — | \$169,813 |
| Non-cash financing activities | | |
| Fair value of warrants issued to placement agent | — | \$369,863 |

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

Since its inception, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure, and has not realized revenues from its planned principal operations. The Company does not anticipate realizing revenues for the foreseeable future. The Company’s activities are subject to the significant risks and uncertainties associated with any specialty pharmaceutical company that has substantial expenditures for research and development, including funding its operations.

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 its sole product, Gimoti™. The Company ended the third quarter of 2017 with approximately \$10.4 million in cash and cash equivalents, and the Company anticipates that it will continue to incur losses from operations due to its plans to fund additional clinical development, including the analysis of data from the comparative exposure pharmacokinetic (“PK”) clinical trial, completion of a planned new drug application (“NDA”) submission for Gimoti, pre-approval and pre-commercialization activities, including marketing and manufacturing of Gimoti, and support its 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 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, 2016, the Company’s independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding the Company’s ability to continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

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 will be sufficient to meet estimated working capital requirements and fund operations through at least June 2018. The Company will need to raise additional debt or equity financing 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, 2016, 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, 2016, which are contained in the Company’s Annual Report on Form 10-K filed with the SEC on March 15, 2017. 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.

The Company also relies on contract research organizations (“CROs”) to manage the analysis of data from the comparative exposure PK trial and the preparation of the planned NDA. If these CROs are unable to continue with this analysis and the management of the NDA preparation, the delays could adversely affect the completion and the timing of the filing of the NDA with FDA.

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

Warrant Accounting

Certain of the warrants to purchase shares of the Company’s common stock, issued as a part of the at-the-market registered direct offerings in July and August 2016, are classified as warrant liability and recorded at fair value. These warrants contain a feature that could require the transfer of cash in the event a change of control occurs without the authorization of our Board of Directors, and therefore, are classified as a liability in accordance with the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 480.

The fair value of each warrant is 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 is 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 is based upon U.S. Treasury securities with remaining terms similar to the expected term of the stock award being valued.

This warrant liability is subject to remeasurement at each balance sheet date and the Company recognizes any change in the fair value of the warrant liability in the statement of operations. The Company will continue to adjust the carrying value of the warrants for changes in the estimated fair value until the earlier of the modification, exercise or expiration of the warrants. At that time, the liabilities will be reclassified to additional paid-in capital, a component of stockholders’ equity. We anticipate that the value of the warrants could fluctuate from quarter to quarter and that such fluctuation could have a material impact on our financial statements.

Stock-Based Compensation

Stock-based compensation expense for stock option grants and employee stock purchases under the Company’s Employee Stock Purchase Plan (the “ESPP”) is recorded at the estimated fair value of the award as of the grant date and is recognized as expense on a straight-line basis over the employee’s requisite service period. The estimation of stock option and ESPP fair value requires management to make estimates and judgments about, among other things, employee exercise behavior, forfeiture rates and volatility of the Company’s common stock. The judgments directly affect the amount of compensation expense that will be recognized.

The Company grants stock options to purchase common stock to employees and members of the board of directors with exercise prices equal to the Company’s closing market price on the date the stock options are granted. The risk-free interest rate assumption was based on the yield of an applicable rate for U.S. Treasury instruments with maturities similar to those of the expected term of the award being valued. The weighted average expected term of options and employee stock purchases was calculated using the simplified method as prescribed by accounting

guidance for stock-based compensation. This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility was calculated based upon the Company's historical volatility, supplemented, 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 assumed dividend yield was based on the Company never paying cash dividends and having no expectation of paying cash dividends in the foreseeable future.

Research and Development Expenses

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

The Company bases its expense accruals related to clinical studies on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on its behalf. The financial terms

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

Included in research and development expenses for the three and nine months ended September 30, 2017 were costs of approximately \$8,000 and \$19,000, respectively, for clinical trial services incurred by a related party of one of the Company's officers. There were no related party costs incurred during the nine months ended September 30, 2016.

The Company does not own or operate manufacturing facilities for the production of Gimoti, nor does it plan to develop its own manufacturing operations in the foreseeable future. The Company currently depends on third-party contract manufacturers for all of its required raw materials, drug substance and finished product for its preclinical research, product development and clinical trials. The Company has agreements with Cosma S.p.A. to supply metoclopramide for the manufacture of Gimoti, and with Thermo Fisher Scientific Inc., who recently acquired Patheon UK Limited, for product development and manufacturing of Gimoti. The Company currently utilizes a third-party consultant, 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 has 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 and 2016. 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 shares subject to repurchase, warrants for the purchase of common stock, options outstanding under the Company's equity incentive plans and potential shares to be purchased under the ESPP. For the periods presented, the following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to do so would be anti-dilutive:

| | Three Months Ended | | Nine Months Ended | |
|------------------------------------|-----------------------|-----------|-----------------------|-----------|
| | September 30, 2017 | 2016 | September 30, 2017 | 2016 |
| Common stock subject to repurchase | 45,000 | 45,000 | 45,000 | 45,000 |
| Warrants to purchase common stock | 2,797,561 | 3,323,876 | 2,771,685 | 3,323,876 |
| Common stock options | 2,131,624 | 1,275,624 | 2,131,624 | 1,275,624 |
| Employee stock purchase plan | 7,064 | 10,938 | 7,064 | 10,938 |

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| | | | | |
|---------------------------|-----------|-----------|-----------|-----------|
| Total excluded securities | 4,981,249 | 4,655,438 | 4,955,373 | 4,655,438 |
|---------------------------|-----------|-----------|-----------|-----------|

For the three and nine months ended September 30, 2017, dilutive shares of 0 and 25,876, respectively, related to the outstanding warrants were included in the diluted net loss per share of common stock calculation.

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. A modified retrospective transition approach is required for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of its pending adoption of the new standard on the Company’s financial statements.

In March 2016, the FASB issued ASU No. 2016-09 Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This guidance changes the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid-in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. The adoption of this guidance on January 1, 2017 did not have a material impact on the Company's financial statements.

3. Debt

On August 4, 2016, the Company repaid in full the entire \$4.5 million of outstanding principal and interest under the Loan and Security Agreement (the "Loan Agreement") between the Company and Square 1 Bank ("Square 1"). In connection with such repayment, the Loan Agreement was terminated, and all security, liens or other encumbrances on assets of the Company were released.

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

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

4. Technology Acquisition Agreement

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

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

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

5. Stockholders' Equity

Sale of Common Stock and Warrants

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

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

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

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

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

On December 15, 2016, the Company entered into amendments (the “Warrant Amendments”) with certain of the holders (the “Holders”) of the Company’s outstanding warrants to purchase common stock issued on July 25, 2016 and August 3, 2016. Pursuant to the Warrant Amendments, the Holders’ right to require the Company to purchase the outstanding warrants upon the occurrence of certain fundamental transactions will not apply if the fundamental transaction is a result of a transaction that has not been approved by the Company’s board of directors. As a result of this amendment, warrants to purchase 252,432 shares of the Company’s common stock were no longer required to be classified as liabilities. The value of amended warrants were adjusted to their fair value immediately prior to the amendment and approximately \$207,000 was reclassified from warrant liability to Additional Paid-in Capital.

On February 16, 2017, an institutional investor from the Company’s 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 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 were adjusted to their fair value immediately prior to the exercise and approximately \$1.4 million was reclassified from warrant liability to Additional Paid-in Capital. Subsequent to this transaction, warrants to purchase 2,449,129 shares of the Company’s common stock remain classified as a liability.

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 led by Laidlaw & Company (UK) Ltd. 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 estimated offering expenses payable by the Company, the net proceeds to the Company from this offering was approximately \$7.3 million.

At the Market Equity Offering Program

On April 15, 2016, the Company terminated its At Market Sales Agreement with MLV & Co. LLC and entered into a new At Market Issuance Sales Agreement with B. Riley FBR, Inc. (as successor by merger to FBR Capital Markets & Co., "FBR") ("FBR Sales Agreement"), and filed a prospectus supplement, pursuant to which the Company may sell from time to time, at its option, up to an aggregate of 649,074 shares of the Company's common stock through FBR as the sales agent. The sales of shares made through this equity program are made in "at-the-market" offerings as defined in Rule 415 of the Securities Act. Through December 31, 2016, the Company sold 56,000 shares of common stock at a weighted average price per share of \$5.45 and received proceeds of approximately \$296,000, net of commissions and fees.

On March 10, 2017, the Company filed a prospectus supplement, which replaced the prospectus supplement filed on April 15, 2016, permitting the Company to sell up to an aggregate of \$20.0 million of shares of its common stock through FBR as a sales agent. Under current SEC regulations, if at the time the Company files its Annual Report on Form 10-K, or Form 10-K, 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 November 3, 2017, the Company's public float was approximately \$49.9 million, based on 12,858,418 shares of outstanding common stock held by non-affiliates and at a price of \$3.88 per share, which was the last reported sale price of the Company's common stock on The Nasdaq

Capital Market on October 11, 2017. 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. The Company had no sales of common stock under the baby shelf rules in the twelve-month period ended November 3, 2017. If the Company's public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease. The Company has not sold any shares of common stock through the FBR Sales Agreement during 2017.

The Company's current Form S-3 shelf registration statement expires on November 25, 2017. Concurrently with filing this Quarterly Report on Form 10-Q, the Company is filing a new shelf registration statement on Form S-3 which extends the effectiveness of the current shelf registration statement until the earlier of the date the SEC declares the new shelf registration statement effective or 6 months from the expiration date of the current shelf registration statement. 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 FBR as a sales agent. The Company remains subject to the limitations of the baby shelf rules described above.

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

As a result of payroll withholdings from the Company's employees of approximately \$135,000 and \$99,000, the Company sold 75,529 and 34,067 shares of common stock through its Employee Stock Purchase Plan ("ESPP") during the nine months ended September 30, 2017 and 2016, respectively.

On May 3, 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.

Stock-Based Compensation

Stock-based compensation expense includes charges related to stock option grants under the Company's 2016 Equity Incentive Award Plan and employee stock purchases under the ESPP. The Company measures stock-based compensation expense based on the grant date fair value of any awards granted to its employees. Such expense is recognized over the period of time that employees provide service and earn rights to the awards.

The estimated fair value of each stock option award granted was determined on the date of grant using the Black Scholes option-pricing valuation model with the following weighted-average assumptions for option grants during the

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three and nine months ended September 30, 2017 and 2016:

| | Three and Nine Months Ended | |
|-------------------------------------|--------------------------------|-----------|
| | September 30, 2017 2016 | |
| Common Stock Options | 1.93% | |
| | - | 1.25% - |
| Risk free interest rate | 2.16% | 1.58% |
| | 5.5 - | |
| Expected option term | 6.0 | 5.3 - 6.0 |
| | years | years |
| | 94.05% | |
| | - | 74.44% - |
| Expected volatility of common stock | 98.25% | 75.91% |
| Expected dividend yield | 0.0% | 0.0% |

There were no stock options granted during the three months ended September 30, 2017 and 2016.

The estimated fair value of each ESPP award was determined on the date of grant using the Black Scholes option-pricing valuation model with the following weighted-average assumptions for option grants during the three and nine months ended September 30, 2017 and 2016:

| | Three Months Ended | | Nine Months Ended | |
|-------------------------------------|--------------------|--------------------|--------------------|--------------------|
| | September 30, 2017 | September 30, 2016 | September 30, 2017 | September 30, 2016 |
| Employee Stock Purchase Plan | | | 0.79% | |
| Risk free interest rate | 1.10% | 0.47% | - | 0.47% |
| Expected term | 6 months | 6 months | 6 months | 6 months |
| Expected volatility of common stock | 37.60% | 212.80% | 37.60% | 83.83% |
| 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, 2017 | September 30, 2016 | September 30, 2017 | September 30, 2016 |
| Research and development | \$200,773 | \$177,767 | \$626,976 | \$487,704 |
| General and administrative | 275,124 | 274,469 | 777,950 | 810,575 |
| Total stock-based compensation expense | \$475,897 | \$452,236 | \$1,404,926 | \$1,298,279 |

As of September 30, 2017, there were approximately \$2.1 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 1.2 years.

6. Fair Value Measurements

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

As noted in Note 5, during the third quarter of 2016 the Company entered into the 2016 Financings with an institutional investor providing for the issuance and sale by the Company of 5,048,632 shares of the Company's common stock and warrants to purchase up to 2,975,444 shares of the Company's common stock for aggregate gross proceeds of \$14.5 million. In addition, as partial payment for services, the Company issued to the underwriters warrants to purchase up to 252,432 shares of the Company's common stock.

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

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

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The Company has classified the warrants as a liability and has remeasured the liability to estimated fair value at September 30, 2017 and December 31, 2016, using the Black Scholes option pricing model with the following assumptions:

| | September 30, | December 31, |
|-------------------------|------------------|-----------------|
| | 2017 | 2016 |
| Risk-free interest rate | 1.77% | 1.93% |
| Expected volatility | 100.41% | 94.19% |
| Expected term | 4.33 years | 5.08 years |
| Expected dividend yield | 0.0% | 0.0% |

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2017 and December 31, 2016:

| | Level 1 | Level 2 | Level 3 | Total |
|-------------------------------|------------|------------|-------------|-------------|
| Warrant liability | | | | |
| Balance at September 30, 2017 | \$ - | \$ - | \$6,050,901 | \$6,050,901 |
| Balance at December 31, 2016 | \$ - | \$ - | \$4,095,019 | \$4,095,019 |

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

| | Warrant Liability |
|--|----------------------|
| Balance at December 31, 2016 | \$4,095,019 |
| Issuance of warrants | — |
| Change in fair value upon re-measurement | 3,354,973 |
| Reclassification to Additional Paid-in Capital | |
| due to warrant exercise | (1,399,091) |
| Balance at September 30, 2017 | \$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, 2016 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 15, 2017. 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 disorders and diseases. We are developing Gimoti, an investigational metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis. Diabetic gastroparesis is a gastrointestinal 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.

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 Gimoti in adult female subjects with diabetic gastroparesis. 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. Preliminary results of the trial showed that Gimoti did not achieve its primary endpoint of symptom improvement at Week 4 in the intent to treat, or ITT, population.

Although the Phase 3 trial failed to reach 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.

In December 2016, we announced we had completed a second pre-new drug application, or 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. The comparative exposure PK trial will serve 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. In March 2017, we met with FDA to discuss the design of the comparative exposure PK trial and certain other chemistry, manufacturing and controls related items associated with the proposed NDA submission.

On October 23, 2017, we announced positive topline results from the comparative exposure PK trial. The objective of the trial was to determine the bioequivalent dose of Gimoti compared to the Reglan Tablets after nasal and oral administration to healthy volunteers under fasted conditions. Based on these results, we expect to submit the Gimoti NDA to FDA in the first quarter of 2018.

The comparative exposure PK trial was an open label, 4-way crossover and enrolled 108 male and female healthy volunteers who were each to receive 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 bioequivalence 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. The maximum observed plasma concentration, or C_{max} , for Gimoti was slightly lower than the bioequivalence range, but in line with expectations that 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.

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 increasing operating losses for at least the next several years. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

As of September 30, 2017 we had cash and cash equivalents of approximately \$10.4 million. We believe our existing cash and cash equivalents will be sufficient to fund our operations through at least June 2018. Current funds on hand are intended to fund clinical development, pre-approval and pre-commercialization activities for Gimoti, including the analysis of data from the comparative exposure PK trial, the planned NDA submission, and for working capital and general corporate purposes.

Technology Acquisition Agreement

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

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

- \$3 million upon the FDA's approval of Gimoti.

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

Financial Operations Overview

Research and Development Expenses

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

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

All of our research and development expenses to date have been incurred in connection with the development of Gimoti. For the remainder of 2017 we expect costs related to our clinical development, including the analysis of data from the comparative exposure PK trial, and pre-approval and pre-commercialization activities, including marketing and manufacturing of Gimoti and completion of a planned NDA submission, to continue. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We are unable to estimate with any certainty the costs we will incur in the continued development of Gimoti. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We may never succeed in achieving marketing approval for our product candidate.

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

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects;
- the number of subjects that participate in the trials;
- the number of doses that subjects receive;
- the cost of comparative agents used in trials;
- the drop-out or discontinuation rates of subjects;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

We do not yet know when Gimoti may be commercially available, if at all.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation. Other general and administrative expenses include professional fees for accounting, tax, patent costs, legal services, insurance, facility costs and costs associated with being a publicly-traded company, including fees associated with investor relations and directors and officers liability insurance premiums. We expect that general and administrative expenses will increase in the future as we expand our operating activities, prepare for the growth needs associated with commercialization and continue to incur additional costs associated with being a publicly-traded company and maintaining compliance with exchange listing and Securities and Exchange Commission requirements. These increases will likely include higher consulting costs, legal fees, accounting fees, directors' and officers' liability insurance premiums and fees associated with investor relations.

Other Income (Expense)

Other income (expense) consists of changes in the fair value of the warrant liability, which represents the change in the fair value of common stock warrants from reporting period to reporting period. The warrant liability relates to the warrants issued in the July 2016 Financing and August 2016 Financing, or collectively the 2016 Financings, and will be revalued each reporting period until the

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liability is settled. We use the Black Scholes pricing model to value the related warrant liability. Other expense in 2016 also included interest expense incurred on our former outstanding debt.

Critical Accounting Policies and Significant Judgments and Estimates

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

The critical accounting policies and estimates underlying the accompanying unaudited financial statements are those set forth in Part II, Item 7 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which was filed with the SEC on March 15, 2017.

Other Information

JOBS Act

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

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 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.

Results of Operations

Comparison of Three Months Ended September 30, 2017 and 2016

The following table summarizes the results of our operations for the three months ended September 30, 2017 and 2016:

| | Three Months Ended | | Increase/ |
|-------------------------------------|--------------------|---------------|-------------|
| | September 30, | September 30, | (Decrease) |
| | 2017 | 2016 | |
| Research and development expenses | \$2,717,698 | \$1,339,343 | \$1,378,355 |
| General and administrative expenses | \$984,047 | \$830,092 | \$153,955 |
| Other expenses | \$1,541,316 | \$855,846 | \$685,470 |

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2017 compared to the three months ended September 30, 2016 increased by approximately \$1.4 million due primarily to our comparative exposure PK trial being conducted during the third quarter of 2017. Our Phase 3 clinical trial was completed during the second quarter of 2016 and the analysis of the trial data occurred during the second half of 2016, so research and development costs were lower during the quarter ended September 30, 2016. Costs incurred in 2017 include 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 related to costs associated with the preparation of an NDA. Costs incurred in 2016 include approximately \$650,000 related

to the Phase 3 clinical trial for Gimoti, approximately \$489,000 for wages, taxes and employee insurance, including approximately \$178,000 of stock-based compensation expense, and approximately \$193,000 related to costs associated with the preparation of an NDA.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2017 compared to the three months ended September 30, 2016 increased by approximately \$154,000. 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. Costs incurred in 2016 primarily included approximately \$446,000 for wages, taxes and employee insurance, including approximately \$274,000 of stock-based compensation expense, and approximately \$319,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

Other Expenses, net. Other expenses for the three months ended September 30, 2017 compared to the three months ended September 30, 2016 increased by approximately \$685,000 due primarily to the increase of approximately \$1.5 million in the fair value of the warrant liability, which resulted in a corresponding increase in other expense. Other expenses for the three months ended September 30, 2016 included approximately \$534,000 of costs related to the 2016 Financings, an increase of approximately \$199,000 in the fair value of the warrant liability, and approximately \$123,000 of interest expense incurred on our former outstanding debt with Square 1 Bank, or Square 1.

Comparison of Nine Months Ended September 30, 2017 and 2016

The following table summarizes the results of our operations for the nine months ended September 30, 2017 and 2016:

| | Nine Months Ended | | |
|-------------------------------------|-----------------------|-----------------------|-----------------------|
| | September 30, 2017 | September 30, 2016 | Increase/ Decrease |
| Research and development expenses | \$5,505,953 | \$5,449,568 | \$56,385 |
| General and administrative expenses | \$3,065,595 | \$2,770,500 | \$295,095 |
| Other expenses | \$3,349,521 | \$1,001,120 | \$2,348,401 |

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 increased by approximately \$56,000. During the first nine months of 2017, we were preparing for and conducting our comparative exposure PK trial, including product development activities and manufacturing Gimoti for such trial. In addition, we also were incurring costs associated with the preparation of an NDA. Costs incurred in 2017 include approximately \$2.1 million of 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 costs associated with the preparation of the NDA. Costs incurred in 2016 include approximately \$3.1 million related to the Phase 3 clinical trial for Gimoti, approximately \$1.5 million for wages, taxes and employee insurance, including approximately \$488,000 of stock-based compensation expense, and approximately \$740,000 related to costs associated with the preparation of an NDA.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 increased by approximately \$295,000. 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. Costs incurred in

2016 primarily included approximately \$1.5 million for wages, taxes and employee insurance, including approximately \$811,000 of stock-based compensation expense, and approximately \$1.1 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

Other Expenses. Other expenses for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 increased by approximately \$2.3 million due primarily to the increase of approximately \$3.4 million in the fair value of the warrant liability, which resulted in a corresponding increase in other expense. Other expenses for the nine months ended September 30, 2016 included approximately \$534,000 of costs related to the 2016 Financings, an increase of approximately \$199,000 in the fair value of the warrant liability and approximately \$268,000 of interest expense incurred on our former outstanding debt with Square 1.

Liquidity and Capital Resources

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

On April 15, 2016, we terminated the MLV Sales Agreement and entered into a new At Market Issuance Sales Agreement with FBR, or the FBR Sales Agreement, and filed a prospectus supplement, pursuant to which we may sell from time to time, at our option up to an aggregate of 649,074 shares of our common stock through FBR as the sales agent. Through December 31, 2016, we sold 56,000 shares of common stock and received net proceeds of approximately \$296,000 under the FBR Sales Agreement. On March 10, 2017, we filed a prospectus supplement, which replaced the prospectus supplement filed on April 15, 2016, permitting us to sell up to an aggregate of \$20.0 million of shares of our common stock through FBR as the sales agent. FBR was subsequently acquired by B. Riley Financial, Inc., or B. Riley. See Item 5 for additional details regarding FBR Sales Agreement.

Our current Form S-3 shelf registration statement expires on November 25, 2017. Concurrently with filing this Quarterly Report on Form 10-Q, we are filing a new shelf registration statement on Form S-3 which extends the effectiveness of the current shelf registration statement until the earlier of the date the SEC declares the new shelf registration statement effective or 6 months from the expiration date of the current shelf registration statement. 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 our common stock through B. Riley (as successor by merger to FBR) as a sales agent. We remain subject to the limitations of the baby shelf rules described below.

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.

We will not be able to make future sales of our common stock pursuant to the FBR Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to FBR under the FBR Sales Agreement. Furthermore, FBR is permitted to terminate the FBR Sales Agreement in its sole discretion upon ten days' notice, or at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on our assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations. We have no obligation to sell the remaining shares available for sale pursuant to the FBR Sales Agreement. However, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than \$75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under the FBR Sales Agreement, is limited to an aggregate of one-third of our public float. As of November 3, 2017, our public float was approximately \$49.9 million, which means we may only sell shares up to one-third of our public float using shelf registration statements in any twelve-month period. We had no sales of common stock under the baby shelf rules in the twelve-month period ended November 3, 2017. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statements will also decrease.

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

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

In August 2016, we completed an at-the-market offering of 3,244,120 shares of common stock at a purchase price of \$3.0825 per share, the August 2016 Financing. Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from an unregistered warrant to purchase one half of a share of our common stock, for a total of 1,622,060 shares, or August Warrants. The August Warrants have an exercise price of \$3.03 per share, are immediately exercisable and will

expire on February 3, 2022. The aggregate gross proceeds from the sale of the common stock and warrants were \$10.0 million, and the net proceeds after deduction of commissions and fees were approximately \$9.2 million.

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

On February 16, 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 were adjusted to their fair value immediately prior to the exercise and approximately \$1.4 million was reclassified from warrant liability to Additional Paid-in Capital. Subsequent to this transaction, warrants to purchase 2,449,129 shares of our common stock remain classified as a liability.

In February and March 2017, we completed the sale of 2,775,861 shares of our common stock in an underwritten public offering led by Laidlaw & Company (UK) Ltd. 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 estimated offering expenses payable by us, the net proceeds to us from this offering was approximately \$7.3 million.

On August 4, 2016, we repaid in full the entire \$4.5 million of outstanding principal and interest under the Loan and Security Agreement, or the Loan Agreement, between us and Square 1. In connection with such repayment, the Loan Agreement was terminated, and all security, liens or other encumbrances on assets of ours were released.

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

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

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, 2016 with respect to our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted our resources to developing 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 at least June 2018. This period could be shortened if there are any significant increases in planned spending on our Gimoti development program, including the analysis of data from our completed comparative exposure PK trial, pre-approval and pre-commercialization activities, including marketing and manufacturing of Gimoti, completion of a planned NDA submission, including whether or not FDA grants our request to waive the user

fees that would otherwise become due upon our filing of an NDA with FDA, 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:

- prepare for and complete further clinical development, including a comparative exposure PK trial in healthy volunteers and the analysis of data from such trial;
- continue the pre-approval and pre-commercialization activities for Gimoti, including the preparation of the NDA;
- continue the preparation of the commercial manufacturing process;

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maintain, expand and protect our intellectual property portfolio; and continue to fund the additional accounting, legal, insurance and other costs associated with being a public company. Although our current cash and cash equivalents are expected to be sufficient to fund our operations through at least June 2018, it may not be sufficient to complete any additional development requirements requested by FDA. Accordingly, we will continue to require substantial additional capital beyond our current cash and cash equivalents to continue our clinical and regulatory development and potential commercialization activities. The amount and timing of our future funding requirements will depend on many factors further described below, including the analysis of the full results of the comparative exposure PK trial, the costs associated with completing and submitting 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 or debt financings or other sources, such as potential collaboration arrangements. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies.

The following table summarizes our cash flows for the nine months ended September 30, 2017 and 2016:

| | Nine Months Ended | |
|---|-------------------|---------------|
| | September 30, | |
| | 2017 | 2016 |
| Net cash used in operating activities | \$(5,983,204) | \$(7,338,098) |
| Net cash provided by financing activities | \$7,389,101 | \$9,026,825 |
| Net increase in cash and cash equivalents | \$1,405,897 | \$1,688,727 |

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 decreased in 2017 as we have been preparing for and conducting our comparative exposure PK clinical trial and the manufacturing of Gimoti for such trial. We expect that cash used in operating activities will increase throughout the remainder of 2017 as those projects, as well as the preparation of the NDA and pre-approval and pre-commercialization activities, continue.

Financing Activities. 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 in an underwritten public offering. In addition, we received proceeds of approximately \$135,000 from the sale of 75,529 shares of common stock through our employee stock purchase plan, or ESPP. During the nine months ended September 30, 2016, we received net proceeds of approximately \$13.2 million through the 2016 Financings from the sale of 5,048,632 shares of common stock and 2,975,444 warrants to purchase our common stock. In addition, we received net proceeds of approximately \$358,000 from the sale of 56,000 shares of common stock pursuant to the FBR Sales Agreement and the sale of 34,067 shares of common stock through our ESPP.

We believe that our existing cash and cash equivalents as of September 30, 2017, together with interest thereon, will be sufficient to meet our anticipated cash requirements through at least June 2018. 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;
- 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;
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;

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- 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 obtain and maintain commercial manufacturing arrangements with third-party manufacturers or establish commercial-scale manufacturing capabilities.

Off-Balance Sheet Arrangements

Through September 30, 2017, 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

In December 2016, we entered into an operating lease for office space in Solana Beach, California. The lease commenced on January 1, 2017 with an expiration date of December 31, 2018. We also pay pass through costs and utility costs, which are expensed as incurred.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

As of September 30, 2017, 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, 2016.

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 Securities and Exchange Commission'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 Securities and Exchange Commission 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, 2017.

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, 2016, other than those set forth below, which should be read in conjunction with the risk factors disclosed therein.

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 second 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. The comparative exposure PK trial will serve as a portion of the full 505(b)(2) data package to include prior efficacy and safety data developed by us and the FDA’s prior findings of safety and efficacy for the Listed Drug, Reglan Tablets. On October 23, 2017, we announced positive topline results from the comparative exposure PK trial and plan to submit the Gimoti NDA during the first quarter of 2018. Although we believe the PK trial establishes bioequivalence, FDA may later determine to require the conduct of additional efficacy or safety trials, and we may be unable to submit an NDA on this timeframe, or potentially at all.

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;
- FDA may disagree with the design of our comparative exposure PK trial or 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 the 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;

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- 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;

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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 obtain and maintain commercial manufacturing arrangements with third-party manufacturers or establish commercial-scale manufacturing capabilities. Of the large number of drugs in development in this industry, only a small percentage result in the submission of an NDA to FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market Gimoti, any such approval may be subject to limitations on the indicated uses for which we may market the product.

We will require substantial additional funding and may be unable to raise capital when needed, which would force us to liquidate, dissolve or otherwise wind down our operations.

Our operations have consumed substantial amounts of cash since inception. We believe, based on our current operating plan, that our existing cash and cash equivalents will be sufficient to fund our operations through at least June 2018, 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 we may initiate based on the analysis of data from our completed comparative exposure PK trial or discussions with FDA, including any additional trials FDA or other regulatory agencies may require evaluating the efficacy or safety of Gimoti;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from FDA, and any similar regulatory agencies, including whether or not FDA grants our request to waive the user fee that would otherwise become due upon our filing of an NDA with FDA;
- 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, should we elect to do so;
- 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.

Topline data may not accurately reflect the complete results of a particular study or trial.

We may publicly disclose topline or interim data from time to time, which is based on a preliminary analysis of then-available data such as the topline results we reported from the comparative exposure PK trial, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or

considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially

different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. For example, while we believe that the AUC measurement is the most clinically relevant PK parameter for this comparative exposure PK trial based on discussions with FDA at previous pre-NDA meetings, the FDA may change their view regarding C_{max} falling below the bioequivalence range of Reglan Tablets as it relates to selecting our dose and more generally in the FDA's review of our planned NDA submission. In addition, the information we may publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Further, although we have reported positive topline data for the PK trial, the FDA may still require the conduct of additional efficacy or safety trials prior to our planned NDA submission.

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

On November 14, 2017, substantially concurrently with this Current Report on Form 10-Q, we will file a shelf registration statement on Form S-3, or the replacement shelf registration statement, with the SEC, which has not yet been declared effective. The replacement registration statement is replacing the registration statement on Form S-3 we originally filed with the SEC on November 13, 2014, which registration statement is set to expire on November 25, 2017. On November 14, 2017, we entered into an amendment, or the Amendment, to the FBR Sales Agreement, pursuant to which sales agreement we may sell from time to time, at our option, shares of common stock through FBR, as sales agent. The Amendment provides, among other things, that sales under the FBR Sales Agreement will be made pursuant to the replacement registration statement, including the base prospectus filed as part of such registration statement, as of and effective upon the SEC declaring such replacement registration statement effective. Sales under the FBR Sales Agreement will continue to be made, if any, pursuant to the original registration statement until the earlier of the effectiveness of the replacement registration statement or 180 days following the expiration of the original registration statement. The Amendment will be effective concurrently with the effectiveness of the replacement shelf registration statement. The foregoing description of the Amendment is not complete and is qualified

in its entirety by reference to the Amendment, a copy of which will be filed as Exhibit 1.2 to the replacement shelf registration statement and is incorporated herein by reference. Please refer to the description of the FBR Sales Agreement in the Liquidity and Capital Resources section contained in Item 2 above. Additional information with respect to the FBR Sales Agreement is available in the current report on Form 8-K filed by us with the SEC on April 15, 2016, and is hereby incorporated by reference. The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the FBR Sales Agreement, a copy of which is filed as Exhibit 1.1 to the current report on Form 8-K filed with the SEC on April 15, 2016.

Item 6. Exhibits

A list of exhibits is set forth below and is incorporated herein by reference.

Exhibit

Number Description of Exhibit

- 3.1 (1) Amended and Restated Certificate of Incorporation of the Company
- 3.2 (1) Amended and Restated Bylaws of the Company
- 4.1 (2) Form of the Company's Common Stock Certificate
- 4.2 (3) Investor Rights Agreement dated as of June 1, 2007
- 4.3 (3) Warrant dated June 1, 2012 issued by the Company to Silicon Valley Bank
- 4.4 (2) Form of Warrant Agreement dated September 30, 2013 issued by the Company to the representative of the underwriters and certain of its affiliates in connection with the closing of the Company's initial public offering
- 4.5 (4) Form of Warrant issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated July 20, 2016
- 4.6 (5) Form of Warrant issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated July 29, 2016
- 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.

*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 14, 2017 By: /s/ David A. Gonyer
David A. Gonyer

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 14, 2017 By: /s/ Matthew J. D'Onofrio
Matthew J. D'Onofrio

Executive Vice President, Chief Business Officer, Treasurer and Secretary

(Principal Financial and Accounting Officer)