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Evoke Pharma Inc
Form 10-Q
May 11, 2016

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 March 31, 2016

OR

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

Commission File Number 001-36075

EVOKE PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

505 Lomas Santa Fe Drive, Suite 270, 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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act:

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

As of April 30, 2016, the registrant had 7,240,918 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

	March 31, 2016 (Unaudited)	December 31, 2015
Assets		
Current Assets:		
Cash and cash equivalents	\$6,099,698	\$8,691,155
Prepaid expenses	764,721	833,276
Other current assets	7,997	—
Total current assets	6,872,416	9,524,431
Other assets	—	7,997
Total assets	\$6,872,416	\$9,532,428
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$1,243,262	\$927,606
Accrued compensation	482,505	760,782
Current portion of long-term debt	708,552	146,052
Total current liabilities	2,434,319	1,834,440
Long-term debt, net of current portion	3,680,921	4,233,059
Total liabilities	6,115,240	6,067,499
Stockholders' Equity:		
Common stock, \$0.0001 par value; authorized shares — 50,000,000; issued and outstanding shares - 7,235,841 and 7,201,774		
at March 31, 2016 and December 31, 2015, respectively	724	720
Additional paid-in capital	52,042,473	51,524,821
Accumulated deficit	(51,286,021)	(48,060,612)
Total stockholders' equity	757,176	3,464,929
Total liabilities and stockholders' equity	\$6,872,416	\$9,532,428

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Operations

(Unaudited)

	Three Months Ended	
	March 31,	
	2016	2015
Operating expenses:		
Research and development	\$2,015,076	\$2,419,961
General and administrative	1,137,753	1,025,261
Total operating expenses	3,152,829	3,445,222
Loss from operations	(3,152,829)	(3,445,222)
Other expense	(72,580)	(75,526)
Net loss	\$(3,225,409)	\$(3,520,748)
Net loss per common share, basic and diluted	\$(0.45)	\$(0.58)
Weighted-average shares used to compute basic and diluted net loss per share	7,168,005	6,103,783

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Cash Flows

(Unaudited)

	Three Months Ended	
	March 31, 2016	2015
Operating activities		
Net loss	\$(3,225,409)	\$(3,520,748)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	418,912	371,600
Non-cash interest	10,362	15,174
Deferred rent expense	—	(3,298)
Change in operating assets and liabilities:		
Prepaid expenses and other assets	68,555	73,333
Accounts payable and accrued expenses	37,379	68,870
Net cash used in operating activities	(2,690,201)	(2,995,069)
Financing activities		
Proceeds from issuance of common stock, net	98,744	531,620
Net cash provided by financing activities	98,744	531,620
Net decrease in cash and cash equivalents	(2,591,457)	(2,463,449)
Cash and cash equivalents at beginning of period	8,691,155	14,155,809
Cash and cash equivalents at end of period	\$6,099,698	\$11,692,360
Supplemental disclosure of cash flow information		
Interest paid	\$62,563	\$41,250
Non-cash financing activities		
Deferred financing costs paid in prior year	—	\$137,812

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Notes to Condensed Financial Statements

(Unaudited)

1. Organization and Basis of Presentation

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

Since its inception, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure, and has not realized revenues from its planned principal operations. The Company does not anticipate realizing revenues for the foreseeable future. The Company’s activities are subject to significant risks and uncertainties, including funding its operations beyond the completion of its ongoing Phase 3 clinical trial for EVK-001.

The Company expects to continue to incur net losses for at least the next several years. The Company will need to raise additional debt or equity financing to fund any additional development requirements requested by the U.S. Food and Drug Administration (“FDA”), as well as for new drug application (“NDA”) preparation, pre-commercial activities, including marketing and manufacturing of EVK-001 and payment of technology acquisition milestones. 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, 2015, which has been derived from audited financial statements, and the unaudited interim condensed financial statements, have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) and follow the requirements of the U.S. Securities and Exchange Commission (“SEC”) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. In management’s opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company’s financial position and its results of operations and its cash flows for the periods presented. These statements do not include all disclosures required by GAAP and should be read in conjunction with the Company’s financial statements and accompanying notes for the year ended December 31, 2015, which are contained in the Company’s Annual Report on Form 10-K filed with the SEC on March 10, 2016. In its report on the Company’s financial statements for the year ended December 31, 2015, the Company’s independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding the Company’s ability to continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. 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.

Stock-Based Compensation

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

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

relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility was calculated based upon the Company's historical volatility, supplemented with historical volatility of comparable companies in the biotechnology industry whose share prices are publicly available for a sufficient period of time. The assumed dividend yield was based on the Company never paying cash dividends and having no expectation of paying cash dividends in the foreseeable future.

Research and Development Expenses

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

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

Included in research and development expenses for the three months ended March 31, 2015 were costs of \$88,025 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 three months ended March 31, 2016.

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

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted-average number of common shares outstanding that are subject to repurchase. The Company has excluded 45,000 shares subject to repurchase from the weighted-average number of common shares outstanding for each of the three months ended March 31, 2016 and 2015. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the

treasury-stock method. Dilutive common stock equivalents are comprised of warrants for the purchase of common stock, options outstanding under the Company's equity incentive plans and potential shares to be purchased under the ESPP. For the periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to do so would be anti-dilutive:

	Three Months Ended	
	March 31,	
	2016	2015
Common stock subject to repurchase	45,000	45,000
Warrants to purchase common stock	118,881	118,881
Common stock options	1,161,624	983,500
Employee stock purchase plan	2,760	3,322
Total excluded securities	1,328,265	1,150,703

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“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 leases for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of its pending adoption of the new standard on the Company’s financial statements.

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

3. Debt

In May 2014, the Company entered into a \$4.5 million loan and security agreement (the “credit facility”) with Square 1 Bank, a division of Pacific Western Bank (“Square 1”), pursuant to which Square 1 agreed to make term loans available to the Company for general corporate and working capital purposes and for capital expenditures.

In December 2014, the Company drew down the entire \$4.5 million. The credit facility bears interest at a fixed annual rate of 5.50%. As a result of an amendment to the credit facility effected on October 5, 2015, the interest-only payment period was extended through November 28, 2016. The outstanding principal balance plus interest will begin amortizing at the end of the interest-only period, with monthly payments of principal and interest being made by the Company to Square 1 in consecutive monthly installments following November 28, 2016 until the credit facility

matures on November 28, 2018. At the Company's option, it may prepay the outstanding principal balance of the credit facility before November 28, 2018 without penalty or premium.

The credit facility includes affirmative and negative covenants applicable to the Company and any subsidiaries created in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and meet certain covenants with respect to enrollment and results of its EVK-001 Phase 3 trial. In September 2015, the Company announced that it had met a patient enrollment covenant requiring enrollment of 75% of the projected total Phase 3 trial enrollment. Prior to receiving positive results from the Phase 3 trial, the Company must either maintain a ratio of its cash at Square 1 to its cash burn over the preceding month of at least 4.00 to 1.00, or the Company must deliver evidence of a forthcoming financing or strategic partnership arrangement to Square 1, in each case in an amount satisfactory to Square 1. After the Company receives positive results from the Phase 3 trial, if at all (which it must achieve on or prior to September 30, 2016), it must either maintain a ratio of its cash at Square 1 to its cash burn over the preceding month of at least 3.00 to 1.00, or the Company must deliver evidence of a forthcoming financing or strategic partnership arrangement to Square 1, in each case in an amount satisfactory to Square 1. The negative covenants include, among others, restrictions on the Company

transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens and selling assets, in each case subject to certain exceptions.

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

In connection with 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. The warrant expires on December 31, 2024. If the warrant has not been exercised prior to its expiration date, it will be deemed to automatically convert by "cashless" conversion. In the event that the Company is acquired, the warrant will be exercisable or deemed automatically converted, which shall be determined based upon whether the Company's successor assumes the obligations of the warrant.

The value determined for the warrant of \$108,122 has been recorded as a debt discount, as well as to stockholders' equity. The debt discount is being amortized to interest expense over the remaining term of the credit facility.

The Company incurred \$82,685 of loan origination costs related to this credit facility. Such costs are being amortized to interest expense over the remaining term of the credit facility.

4. Technology Acquisition Agreement

In June 2007, the Company acquired all worldwide rights, data, patents and other related assets associated with EVK-001 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 EVK-001. 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 EVK-001 achieves the following development targets:

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

The remaining \$47 million in milestone payments depend on EVK-001's commercial success and will only apply if EVK-001 receives regulatory approval. In addition, the Company will be required to pay to Mallinckrodt a low single digit royalty on net sales of EVK-001. The Company's obligation to pay such royalties will terminate upon the expiration of the last patent right covering EVK-001, which is expected to occur in 2030.

5. Stockholders' Equity

In November 2014, the Company entered into an At Market Sales Agreement with MLV & Co. LLC ("MLV") ("MLV Sales Agreement"), pursuant to which the Company could sell from time to time, at its option, up to an aggregate of \$6.6 million worth of shares of common stock through MLV as sales agent. During September 2015, FBR & Co.

(“FBR”), acquired MLV. The sales of shares of the Company’s common stock made through this equity program were made in “at-the-market” offerings as defined in Rule 415 of the Securities Act of 1933, as amended (the “Securities Act”). During the year ended December 31, 2015, the Company sold 1,048,507 shares of common stock at a weighted average price per share of \$4.78 pursuant to the MLV Sales Agreement and received proceeds of approximately \$4.9 million, net of commissions and fees. The Company did not sell any shares of common stock through the MLV Sales Agreement during the three months ended March 31, 2016. The Company incurred approximately \$138,000 of legal, accounting and filing fees related to its Registration Statement on Form S-3 filed in November 2014. Such costs were capitalized and included in other current assets at December 31, 2014, and were reclassified to additional paid-in capital during the first quarter of 2015 as a further offset to the net proceeds. The Company intends to use the net proceeds to continue to fund its ongoing Phase 3 clinical trial and for general corporate purposes.

On April 15, 2016, the Company terminated the MLV Sales Agreement and entered into a new At Market Issuance Sales Agreement with FBR (“FBR Sales Agreement”), pursuant to which the Company may sell from time to time, at its option, up to an aggregate of 649,074 shares of the Company’s common stock through FBR as the sales agent. The sales of shares made through this equity program are made in “at-the-market” offerings as defined in Rule 415 of the Securities Act. Future sales will depend on a variety of

factors including, but not limited to, market conditions, the trading price of the Company's common stock and the Company's capital needs. Although sales of the Company's common stock have taken place pursuant to the MLV Sales Agreement, and are continuing pursuant to the FBR Sales Agreement, there can be no assurance that FBR will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that the Company deems appropriate. Under current SEC regulations, at any time during which the aggregate market value of the Company's common stock held by non-affiliates, or public float, is 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, including sales under the FBR Sales Agreement, is limited to an aggregate of one-third of the Company's public float. As of April 30, 2016, the Company's public float was approximately 4.2 million shares, the value of which was approximately \$23.1 million based upon the closing price of the Company's common stock of \$5.50 on April 5, 2016. The value of one-third of the Company's public float calculated on the same basis was approximately \$7.7 million.

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.

As a result of payroll withholdings from the Company's employees of approximately \$99,000 and \$111,000, the Company sold 34,067 and 23,288 shares of common stock through its ESPP during the three months ended March 31, 2016 and 2015, respectively.

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

Stock-Based Compensation

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

The estimated fair value of each stock option award granted was determined on the date of grant using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for option grants during the three months ended March 31, 2016 and 2015:

	Three Months Ended	
	March 31, 2016	2015
Stock Options		
Risk free interest rate	1.25%	1.87%
	-	

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	1.575%	
	5.3 -	
	6.0	6.0
Expected option term	years	years
	74.44%	
	-	
Expected volatility of common stock	75.91%	71.99%
Expected dividend yield	0.0%	0.0%

The estimated fair value of each ESPP award was determined on the date of grant using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for option grants during the three months ended March 31, 2016 and 2015.

	Three Months Ended	
	March 31, 2016	2015
Employee Stock Purchase Plan		
Risk free interest rate	0.50%	0.08%
	6.0	6.0
Expected term	months	months
Expected volatility of common stock	83.83%	62.91%
Expected dividend yield	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	
	March 31,	
	2016	2015
Research and development	\$ 158,788	\$ 143,024
General and administrative	260,124	228,576
Total stock-based compensation expense	\$ 418,912	\$ 371,600

In February 2016, the Company effected a one-time option exchange, wherein employees were offered the opportunity to exchange certain outstanding stock options for the grant of a lesser number of replacement stock options. The participants received three new stock options for every four stock options tendered for exchange. As a result, 703,500 stock options were exchanged for 527,624 replacement stock options. The 175,876 stock options that were not reissued may be granted in the future. The replacement stock options have a three-year vesting schedule and an exercise price of \$3.04 per share, which was the closing price of the Company's common stock on the date of the option exchange. All other terms of the replacement stock options remain the same as the original stock options that were exchanged. As a result of this transaction, the Company recognized an incremental stock-based compensation expense of approximately \$4,700 at the time of the transaction and will recognize an additional approximately \$141,000 of stock-based compensation expense over the three-year vesting term of the exchanged options.

As of March 31, 2016, there were approximately \$2.7 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 1.3 years.

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

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2015 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 10, 2016. Past operating results are not necessarily indicative of results that may occur in future periods.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statement. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. As a result of many factors, including without limitation those set forth under "Risk Factors" under Item 1A of Part II below, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. Except as required by applicable law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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

Overview

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

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

We believe nasal administration has the potential to provide our target population of gastroparesis patients with a preferred treatment option for several important reasons: (1) unlike metoclopramide tablets which may have erratic absorption due to gastroparesis itself, EVK-001 is designed to bypass the digestive system to allow for more predictable drug absorption, even when patients are vomiting; (2) the absorption of EVK-001 occurs across the thin mucosa in the nasal cavity to allow for rapid and predictable drug administration through the nasal route; and (3) for gastroparesis patients experiencing nausea, a nasal spray may be better tolerated than an oral medication.

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

In April 2014, we commenced enrollment in a Phase 3 clinical trial of EVK-001 in female subjects with symptoms associated with acute and recurrent diabetic gastroparesis. This Phase 3 clinical trial is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluating the efficacy, safety and population pharmacokinetics of EVK-001 in adult female subjects with diabetic gastroparesis when dosed four times a day for 28 days. On April 25, 2016, we announced that the Phase 3 trial has completed enrollment. A total of 205 subjects were randomized in this trial. We expect to provide top line results from this trial early in the third quarter of 2016. If the results from this trial are positive, we plan to submit a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for EVK-001. If the FDA accepts the NDA filing for review, we would owe a \$1.5 million milestone payment related to the acquisition of our technology. FDA approval of the NDA is required in order for us to commercially market EVK-001 in the United States.

We successfully completed a thorough ECG (QT/QTc) trial and reported positive results in December 2014. A thorough ECG (QT/QTc) trial is a specialized clinical trial designed to assess whether a drug has the potential to prolong the QT interval. The QT interval represents the amount of time the heart's electrical system takes to repolarize, or recharge, after each beat, and the QTc interval represents the QT interval corrected for differences in heart rate. Prolongation of the QT interval may increase the risk for cardiac arrhythmias. Data from the thorough ECG (QT/QTc) trial met the pre-specified primary endpoint, demonstrating that EVK-001, at therapeutic and supratherapeutic doses, did not prolong the QT/QTc interval in healthy subjects.

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

We have no products approved for sale, and we have not generated any revenue from product sales or other arrangements. We have primarily funded our operations through the sale of our convertible preferred stock, borrowings under our loan and security agreements and the sale of shares of our common stock on the NASDAQ Capital Market. We have incurred losses in each year since our inception. Substantially all of our operating losses resulted from expenses incurred in connection with advancing EVK-001 through development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

As of March 31, 2016 we had cash and cash equivalents of \$6.1 million. We expect to be able to fund our operations through October 2016, but we will need to raise additional capital to fund any additional development requirements requested by the FDA, as well as for NDA preparation, pre-commercial activities, including marketing and manufacturing of EVK-001, and payment of technology acquisition milestones. As more fully described in Note 5 to the condensed financial statements, in November 2014 we entered into a sales agreement with MLV & Co. LLC, or the MLV Sales Agreement, which was subsequently acquired by FBR & Co., or FBR, pursuant to which we could have sold, at our option, up to an aggregate of \$6.6 million worth of shares of common stock through FBR, as sales agent. As of March 31, 2016, we had sold 1,048,507 shares of our common stock pursuant to the MLV Sales Agreement and received proceeds of approximately \$4.9 million, net of commissions and fees.

On April 15, 2016, we terminated the MLV Sales Agreement and entered into a new At Market Issuance Sales Agreement with FBR, or the FBR Sales Agreement, pursuant to which we may sell from time to time, at our option, up to an aggregate of 649,074 shares of our common stock through FBR as sales agent. Though we may have the capacity to make sales of our common stock under the FBR Sales Agreement in the future, we may not be able to raise additional capital on terms acceptable to us, or at all. Any failure to raise capital as and when needed could have a material adverse effect on our results of operations, financial condition, cash flows and our ability to execute on our business plan. In its report on our financial statements for the year ended December 31, 2015, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern.

Technology Acquisition Agreement

In June 2007, we acquired all worldwide rights, data, patents and other related assets associated with EVK-001 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 EVK-001. In August 2014, Mallinckrodt, plc, or Mallinckrodt, acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the asset purchase agreement with 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 EVK-001 achieves the following development targets:

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

The remaining \$47 million in milestone payments depend on EVK-001's commercial success and will only apply if EVK-001 receives regulatory approval. In addition, we will be required to pay to Mallinckrodt a low single digit royalty on net sales of EVK-001. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering EVK-001, which is expected to occur in 2030.

Financial Operations Overview

Research and Development Expenses

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

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

All of our research and development expenses to date have been incurred in connection with EVK-001. Despite completion of our Phase 3 clinical trial enrollment in women, and pending results of our Phase 3 clinical trial, we expect our research and development expenses to remain consistent for the remainder of 2016, as the costs related to our NDA preparation activities and our pre-commercial activities, including marketing and manufacturing of EVK-001, are expected to increase, but such increase in costs will be offset by the decrease in clinical trial costs. In addition, should the FDA accept our NDA filing, we would owe Mallinckrodt a \$1.5 million milestone payment. Such payment would be recorded as a research and development expense when incurred. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We are unable to estimate with any certainty the costs we will incur in the continued development of EVK-001. However, we currently estimate that the costs of our Phase 3 clinical trial in women and our companion clinical trial in men will be approximately \$16.5 million, of which, through March 31, 2016, \$15.1 million have been incurred related to those clinical activities. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We may never succeed in achieving marketing approval for our product candidate.

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

per patient trial costs;
the number of sites included in the trials;
the countries in which the trials are conducted;
the length of time required to enroll eligible 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 EVK-001 may be commercially available, if at all.

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General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation. Other general and administrative expenses include professional fees for accounting, tax, patent costs, legal services, insurance, facility costs and costs associated with being a publicly-traded company. We expect that general and administrative expenses will increase in the future as we expand our operating activities, 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 SEC requirements. These increases will likely include higher consulting costs, legal fees, accounting fees, directors and officers liability insurance premiums and fees associated with investor relations.

Total Other Expense

Total other expense consists primarily of interest expense incurred on our 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.

There were no significant changes during the three months ended March 31, 2016 to the critical accounting policies described in "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

Other Information

JOBS Act

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

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight

Board, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more, (b) the last day of our fiscal year following the fifth anniversary of the date of the completion of our 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 March 31, 2016 and 2015

The following table summarizes the results of our operations for the three months ended March 31, 2016 and 2015:

	Three Months Ended		Increase/
	March 31,	March 31,	(Decrease)
	2016	2015	
Research and development	\$2,015,076	\$2,419,961	\$(404,885)
General and administrative	\$1,137,753	\$1,025,261	\$112,492
Other expense	\$72,580	\$75,526	\$(2,946)

Research and Development Expenses. Research and development expenses for the three months ended March 31, 2016 compared to the three months ended March 31, 2015 decreased by approximately \$405,000 primarily due to higher outside clinical trial and consultant costs incurred during the first quarter of 2015. Costs incurred in 2016 include approximately \$1.3 million related to our ongoing clinical trials and approximately \$542,000 for wages, taxes and employee insurance, including approximately \$159,000 of stock-based compensation expense. Costs incurred in 2015 include approximately \$1.7 million related to the clinical trials for EVK-001, approximately \$540,000 for wages, taxes and employee insurance, including approximately \$143,000 of stock-based compensation expense, and approximately \$179,000 related to the production of EVK-001.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2016 compared to the three months ended March 31, 2015 increased by approximately \$112,000 due primarily to an increase in stock-based compensation and professional fees. Costs incurred in 2016 primarily included approximately \$552,000 for wages, taxes and employee insurance, including approximately \$260,000 of stock-based compensation expense and approximately \$523,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. Costs incurred in 2015 primarily included approximately \$481,000 for wages, taxes and employee insurance, including approximately \$229,000 of stock-based compensation expense, and approximately \$446,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

Other Expense. Other expense for the three months ended March 31, 2016 and March 31, 2015, consists primarily of interest expense incurred on our outstanding debt.

Liquidity and Capital Resources

Since our inception in 2007, we have funded our operations primarily from the sale of equity securities and borrowings under loan and security agreements. Prior to our IPO, we received \$17.7 million in net proceeds from the sale of our Series A convertible preferred stock and advances of \$5.5 million under the loan and security agreements. During 2013, we completed our IPO and raised approximately \$25.1 million, net of offering costs and commissions, and during 2015, we raised approximately \$4.9 million, net of costs and commissions from sales of our common stock pursuant to the MLV Sales Agreement. We have incurred losses since inception and have negative cash flows from operating activities. As of March 31, 2016, we had approximately \$6.1 million in cash and cash equivalents and working capital of approximately \$4.4 million.

In May 2014, we entered into a loan and security agreement, or the credit facility, with Square 1 Bank, a division of Pacific Western Bank, or Square 1, pursuant to which Square 1 agreed to make term loans available to us for general corporate and working capital purposes and for capital expenditures, in a principal amount of up to \$4.5 million.

In December 2014, we drew down the entire \$4.5 million. The credit facility bears interest at a fixed annual rate of 5.50%. As a result of an amendment to the credit facility effected in October 2015, the interest-only payment period was extended through November 28, 2016. The outstanding principal balance plus interest will begin amortizing at the end of the interest-only period, with monthly payments of principal and interest being made by us to Square 1 in consecutive monthly installments following November 28, 2016 until the credit facility matures on November 28, 2018. At our option, we may prepay the outstanding principal balance of the credit facility before November 28, 2018 without penalty or premium.

The credit facility includes affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and meet certain covenants with respect to enrollment and results of our EVK-001 Phase 3 trial. In September 2015, we announced that we had met a patient enrollment covenant requiring enrollment of 75% of the projected total Phase 3 trial enrollment. Prior to receiving positive results from the Phase 3 trial, we must either maintain a ratio

of our cash at Square 1 to our cash burn over the preceding month of at least 4.00 to 1.00, or we must deliver evidence of a forthcoming financing or strategic partnership arrangement to Square 1, in each case in an amount satisfactory to Square 1. After we receive positive results from the Phase 3 trial, if at all (which we must achieve on or prior to September 30, 2016), we must either maintain a ratio of our cash at Square 1 to our cash burn over the preceding month of at least 3.00 to 1.00, or we must deliver evidence of a forthcoming financing or strategic partnership arrangement to Square 1, in each case in an amount satisfactory to Square 1. The negative covenants include, among others, restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens and selling assets, in each case subject to certain exceptions.

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

In connection with 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. The warrant will expire ten years from its date of issuance. If the warrant has not been exercised prior to its expiration date, it will be deemed to automatically convert by “cashless” conversion. In the event that we are acquired, the warrant will be exercisable or deemed automatically converted, which shall be determined based upon whether our successor assumes the obligations of the warrant.

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

- continue our clinical trials associated with EVK-001, including our ongoing Phase 3 clinical trial in women and the companion clinical trial in men that we commenced in April 2014;
- continue the preparation of the commercial manufacturing process;
- continue our NDA preparation process, which would also include a \$1.5 million payment to Mallinckrodt should the FDA accept our NDA filing;
- continue our pre-commercial launch activities;
- 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 October 2016, which includes the reporting of Phase 3 clinical trial results, they will not be sufficient to complete any additional development requirements requested by the FDA, or, if applicable, to prepare for commercialization of EVK-001 should we receive product approval. Accordingly, we will continue to require substantial additional capital beyond our current cash and cash equivalents to continue our clinical development and potential commercialization activities. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources, such as potential collaboration arrangements. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies.

In November 2014, we entered into the MLV Sales Agreement, 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. Through March 31, 2016, 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 intend to use the net proceeds to continue to fund our ongoing Phase 3 clinical trial, report the results of that trial, continue preparation of the NDA, and for general corporate purposes.

On April 15, 2016, we terminated the MLV Sales Agreement and entered into the FBR Sales Agreement, pursuant to which we may sell from time to time, at our opinion, up to an aggregate of 649,074 shares of our common stock through FBR as the sales agent. Future sales will depend on a variety of factors including, but not limited to, market conditions, the trading price of our common stock and our capital needs. Although sales of our common stock have taken place pursuant to the MLV Sales Agreement and are continuing pursuant to the FBR Sales Agreement, there can be no assurance that FBR will be successful in consummating future sales

based on prevailing market conditions or in the quantities or at the prices that we deem appropriate. 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 April 30, 2016, our public float was approximately 4.2 million shares, the value of which was approximately \$23.1 million based upon the closing price of our common stock of \$5.50 on April 5, 2016. The value of one-third of our public float calculated on the same basis was approximately \$7.7 million.

We will not be able to make future sales of our common stock pursuant to the FBR Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to FBR under the FBR Sales Agreement. Furthermore, FBR is permitted to terminate the FBR Sales Agreement in its sole discretion upon ten days' notice, or at any time in certain circumstances, including the occurrence of an event that would be reasonably likely to have a material adverse effect on our assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations. We have no obligation to sell the remaining shares available for sale pursuant to the FBR Sales Agreement.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2015 with respect to this uncer