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, 2019

OR

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

Commission File Number 001-36075

EVOKE PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-8447886**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**
420 Stevens Avenue, Suite 370, Solana Beach, CA	**92075**
(Address of principal executive offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Exchange Act

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	EVOK	The Nasdaq Capital Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange 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 October 31, 2019, the registrant had 24,231,914 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, 2019 (Unaudited)	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 6,504,802	$ 5,319,004
Prepaid expenses	775,607	329,218
Other current assets	11,551	—
Total current assets	7,291,960	5,648,222
Operating lease right-of-use asset	35,398	—
Other assets	—	11,551
Total assets	$ 7,327,358	$ 5,659,773
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 1,154,520	$ 476,202
Accrued compensation	964,243	1,158,251
Operating lease liability	35,398	—
Total current liabilities	2,154,161	1,634,453
Stockholders' equity:		
Common stock, $0.0001 par value; authorized shares - 50,000,000; issued and outstanding shares - 24,231,914 and 17,427,533 at September 30, 2019 and December 31, 2018, respectively	2,423	1,743
Additional paid-in capital	89,482,936	82,628,312
Accumulated deficit	(84,312,162)	(78,604,735)
Total stockholders' equity	5,173,197	4,025,320
Total liabilities and stockholders' equity	$ 7,327,358	$ 5,659,773

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Operations

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 822,444	$ 625,497	$ 2,774,924	$ 3,399,654
General and administrative	814,218	897,060	2,955,371	2,846,611
Total operating expenses	1,636,662	1,522,557	5,730,295	6,246,265
Loss from operations	(1,636,662)	(1,522,557)	(5,730,295)	(6,246,265)
Other income:				
Interest income	8,597	3,089	22,868	7,425
Gain from change in fair value of warrant liability	—	—	—	433,392
Total other income	8,597	3,089	22,868	440,817
Net loss	$ (1,628,065)	$ (1,519,468)	$ (5,707,427)	(5,805,448)
Net loss per share of common stock, basic and diluted	$ (0.07)	$ (0.09)	$ (0.26)	$ (0.36)
Weighted-average shares used to compute basic and diluted net loss per share	24,128,060	17,129,649	21,623,648	16,327,385

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Stockholders' Equity

(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2019	17,427,533	$ 1,743	$ 82,628,312	$ (78,604,735)	$ 4,025,320
Stock-based compensation expense	—	—	378,959	—	378,959
Issuance of common stock, net	450,000	45	636,387	—	636,432
Net loss	—	—	—	(1,965,266)	(1,965,266)
Balance at March 31, 2019	17,877,533	1,788	83,643,658	(80,570,001)	3,075,445
Stock-based compensation expense	—	—	344,841	—	344,841
Issuance of common stock, net	6,236,423	623	5,039,333	—	5,039,956
Net loss	—	—	—	(2,114,096)	(2,114,096)
Balance at June 30, 2019	24,113,956	2,411	89,027,832	(82,684,097)	6,346,146
Stock-based compensation expense	—	—	331,303	—	331,303
Issuance of common stock, net	117,958	12	123,801	—	123,813
Net loss	—	—	—	(1,628,065)	(1,628,065)
Balance at September 30, 2019	24,231,914	$ 2,423	$ 89,482,936	$ (84,312,162)	$ 5,173,197

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2018	15,413,610	$ 1,541	$ 73,202,863	$ (71,038,655)	$ 2,165,749
Stock-based compensation expense	—	—	393,775	—	393,775
Issuance of common stock, net	268,870	27	544,616	—	544,643
Reclassification of warrant liability due to warrant amendment	—	—	3,267,885	—	3,267,885
Net loss	—	—	—	(1,982,786)	(1,982,786)
Balance at March 31, 2018	15,682,480	1,568	77,409,139	(73,021,441)	4,389,266
Stock-based compensation expense	—	—	387,429	—	387,429
Issuance of common stock, net	1,216,184	122	2,886,755	—	2,886,877
Net loss	—	—	—	(2,303,194)	(2,303,194)
Balance at June 30, 2018	16,898,664	1,690	80,683,323	(75,324,635)	5,360,378
Stock-based compensation expense	—	—	380,062	—	380,062
Issuance of common stock from employee stock purchase plan	28,869	3	47,054	—	47,057
Issuance of common stock, net	500,000	50	1,139,670	—	1,139,720
Net loss	—	—	—	(1,519,468)	(1,519,468)
Balance at September 30, 2018	17,427,533	$ 1,743	$ 82,250,109	$ (76,844,103)	$ 5,407,749

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.

Condensed Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities		
Net loss	$ (5,707,427)	$ (5,805,448)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,055,103	1,161,266
Change in fair value of warrant liability	—	(433,392)
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(345,975)	(187,911)
Accounts payable and other current liabilities	383,896	(464,161)
Net cash used in operating activities	(4,614,403)	(5,729,646)
Financing activities		
Proceeds from issuance of common stock, net	5,800,201	4,618,297
Net cash provided by financing activities	5,800,201	4,618,297
Net increase (decrease) in cash and cash equivalents	1,185,798	(1,111,349)
Cash and cash equivalents at beginning of period	5,319,004	7,679,267
Cash and cash equivalents at end of period	$ 6,504,802	$ 6,567,918
Non-cash financing activities		
Reclassification of warrant liability to equity due to amendment of warrants	—	$ 3,267,885

See accompanying notes to these unaudited condensed financial statements.

1. Organization and Basis of Presentation

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

Since its inception, the Company has devoted substantially all of its efforts to developing its sole product candidate, Gimoti™, and has not realized revenues from its planned principal operations. The Company filed a 505(b)(2) New Drug Application ("NDA") for Gimoti with the U.S. Food and Drug Administration ("FDA") on June 1, 2018, and on April 1, 2019, the Company received a Complete Response Letter ("CRL") from FDA for the NDA. The CRL stated that FDA has determined it cannot approve the NDA in its present form and provided recommendations to address the two remaining approvability issues in an NDA resubmission. The approvability issues are related to clinical pharmacology and product quality/device quality. FDA did not request any new clinical data and did not raise any safety concerns.

On July 25, 2019, the Company completed a type A meeting with FDA to obtain FDA's feedback and agreement on the Company's plan to address deficiencies cited in the CRL in support of a resubmission of the Gimoti NDA. The focus of the discussion was on topics noted in the CRL, including the root cause analysis of low drug exposure in the comparative bioavailability study and additional product quality/device quality control testing.

Based on FDA feedback and the meeting minutes, the Company will include its root cause analysis and previously collected patient use and experience information in its resubmission package. The Company also agreed to provide an analysis of pump performance characteristics on the nasal spray devices used in the comparative bioavailability study and 3-month stability data from commercial scale batches of Gimoti which the Company initiated manufacturing in June 2019 and completed manufacturing in September 2019. No additional human clinical trials were requested by FDA. The Company plans to resubmit the Gimoti NDA in the fourth quarter of 2019.

The Company does not anticipate realizing revenues until FDA approves the NDA and the Company begins commercializing Gimoti, which events may never occur. The Company's activities are subject to the significant risks and uncertainties associated with any specialty pharmaceutical company that has substantial expenditures for research and development, including funding its operations.

Going Concern

The Company has incurred recurring losses and negative cash flows from operations since inception and expects to continue to incur net losses for the foreseeable future until such time, if ever, that it can generate significant revenues from the sale of Gimoti. Although the Company ended the third quarter of 2019 with approximately $6.5 million in cash and cash equivalents, the Company anticipates that it will continue to incur losses from operations due to pre-approval and pre-commercialization activities, including interactions with FDA on the Company's NDA submission for Gimoti, responding to approvability issues raised in the CRL received from FDA, and potentially manufacturing commercial batches of Gimoti, and for general and administrative costs to support operations. As a result, the Company believes that there is substantial doubt about its ability to continue as a going concern for one year after the date these financial statements are issued.

The determination as to whether the Company can continue as a going concern contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. In its report on the Company's financial statements for the year ended December 31, 2018, the Company's independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern.

The Company's net losses may fluctuate significantly from quarter to quarter and year to year. The Company believes, based on its current operating plan, that its existing cash and cash equivalents will be sufficient to fund its operations into the second quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the Novos Growth, LLC ("NGP") Working Capital Loan and the NGP Credit Agreement, as disclosed in Note 6. Under either situation, the Company will be required to raise additional funds through debt, equity or other forms of financing, such as potential collaboration arrangements, to fund future operations and continue as a going concern.

There can be no assurance that additional financing will be available when needed or on acceptable terms. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations, financial condition and future prospects. There can be no assurance that the Company will be able to further develop Gimoti, if required, and resubmit and receive FDA approval of the Gimoti NDA. Because the Company's business is entirely dependent on the success of Gimoti, if the Company is unable to secure additional financing or identify and execute on other

development or strategic alternatives for Gimoti or our company, the Company will be required to curtail all of its activities and may be required to liquidate, dissolve or otherwise wind down its operations.

Notice of Delisting

On May 15, 2019, the Company received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on The Nasdaq Capital Market.

In accordance with Nasdaq listing rules, the Company has been provided an initial period of 180 calendar days, or until November 11, 2019, to regain compliance. The letter states that Nasdaq will provide written notification that the Company has achieved compliance with its rules if at any time before November 11, 2019, the bid price of the Company's common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. The Nasdaq letter has no immediate effect on the listing or trading of the Company's common stock and the common stock will continue to trade on The Nasdaq Capital Market.

The Company does not expect to regain compliance with Nasdaq listing rules by November 11, 2019, but the Company may be eligible for an additional 180 calendar day compliance period. To qualify, the Company will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. The Company intends to provide such notice prior to the expiration of the initial compliance period and as of the date of this report the Company meets the continued listing requirements, other than the bid price requirement. However, if it appears to Nasdaq that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq would notify the Company that its securities would be subject to delisting. In the event of such a notification, the Company may appeal Nasdaq's determination to delist its securities, but there can be no assurance Nasdaq would grant the Company's request for continued listing.

2. Summary of Significant Accounting Policies

The accompanying condensed balance sheet as of December 31, 2018, 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, 2018, which are contained in the Company's Annual Report on Form 10-K filed with the SEC on March 6, 2019. The results for interim periods are not necessarily indicative of the results expected for the full fiscal year or any other interim period.

Use of Estimates

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

Contract Research Organizations and Consultants

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

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

The Company also relies on third-party sales and marketing organizations for the management of the pre-commercial launch preparation for Gimoti, as well as for a dedicated sales team to sell Gimoti, if approved by FDA. If such third-party organizations are unable to continue managing the launch preparation, or serving as a dedicated sales team, the commercialization of Gimoti could be materially and adversely affected.

Warrant Accounting

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

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

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

Stock-Based Compensation

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

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

Research and Development Expenses

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

The Company does not own or operate manufacturing facilities for the production of Gimoti, nor does it plan to develop its own manufacturing operations in the foreseeable future. The Company currently depends on third-party contract manufacturers for all of its required raw materials, drug substance and finished product for its pre-commercial product development. The Company has agreements with Cosma S.p.A. to supply metoclopramide for the manufacture of Gimoti, and with Thermo Fisher Scientific Inc., who acquired Patheon UK Limited, for product development and manufacturing of Gimoti. The Company currently utilizes third-party consultants, which it engages on an as-needed, hourly basis, to manage product development and manufacturing contractors.

Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Common stock subject to repurchase	—	—	—	25,055
Warrants to purchase common stock	2,713,561	2,713,561	2,713,561	2,713,561
Common stock options	3,114,371	3,017,624	3,114,371	3,017,624
Employee stock purchase plan	7,294	2,697	7,294	2,697
Total excluded securities	5,835,226	5,733,882	5,835,226	5,758,937

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842). 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. The Company adopted this standard effective January 1, 2019, as required. The Company determines if an arrangement is a finance lease, operating lease or short-term lease at inception. The Company elected the "package of practical expedients," which permits the Company not to reassess prior conclusions about lease identifications, lease classification and initial direct costs. The Company also elected not to separate lease and non-lease components when certain conditions are met. As discussed in Note 3, the Company's only significant lease is its facility lease, which expires on December 31, 2019, and is classified as an operating lease.

3. Commitments

Facility Lease

In December 2016, the Company entered into an operating lease for office space in Solana Beach, California. The lease commenced on January 1, 2017, was extended in September 2018 and has an expiration date of December 31, 2019. According to ASU No. 2016-02, the Company recognized an operating lease ROU asset and liability based on the present value of the future minimum lease payments over the lease term at the commencement date, using the Company's assumed incremental borrowing rate, and then amortizes the ROU assets and liabilities over the lease term. The Company applies a discount rate to the minimum lease payments within the lease agreement to determine the value of right-of-use assets and lease liabilities. Unless the rate implicit in the lease is determinable, ASU No. 2016-02 requires the use of the rate of interest that a lessee would have to pay to borrow on a collateralized basis over a similar term for a similar amount to the lease payments in a similar economic environment. The Company noted that the implicit rate in the lease was not determinable and calculated its incremental borrowing rate primarily based on the Company's assumed borrowing rate of 12%. On January 1, 2019, the Company recorded an operating lease ROU asset and liability of approximately $136,000 based on the present value of the remaining minimum lease payments. During the nine months ended September 30, 2019, operating lease ROU asset and liability were included in prepaid expenses and other assets and accounts payable and other current liabilities, respectively, on the statement of cash flows.

Rent expense for the three months ended September 30, 2019 and 2018 was approximately $36,000 and $35,000, respectively. Rent expense for the nine months ended September 30, 2019 and 2018 was approximately $109,000 and $104,000, respectively. The Company also pays pass through costs and utility costs, which are expensed as incurred.

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

The remaining $47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, the Company will be required to pay Mallinckrodt a low single digit royalty on net sales of Gimoti. The Company's obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2032.

5. Stockholders' Equity

At the Market Equity Offering Program

In November 2017, the Company filed a shelf registration with the SEC on Form S-3. The shelf registration statement includes a prospectus for the at-the-market offering to sell up to an aggregate of $16.0 million of shares of the Company's common stock through B. Riley FBR, Inc. ("FBR") as a sales agent (the "FBR Sales Agreement"). During the nine months ended September 30, 2018, the Company sold 1,985,054 shares of common stock at a weighted-average price per share of $2.38 pursuant to the FBR Sales Agreement and received proceeds of approximately $4.6 million, net of commissions and fees. During the nine months ended September 30, 2019, the Company sold 6,804,381 shares of common stock at a weighted-average price per share of $0.87 pursuant to the FBR Sales Agreement and received proceeds of approximately $5.8 million, net of commissions and fees.

Future sales will depend on a variety of factors including, but not limited to, market conditions, the trading price of the Company's common stock and the Company's capital needs. 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.

Warrants

In March 2018, the Company entered into the Warrant Amendments with each of the holders of the Company's outstanding Warrants acquired as a part of the Company's financings which closed in July and August 2016. As a result of the Warrant Amendments, all of the remaining Warrants to purchase 2,449,129 shares of the Company's common stock are no longer required to be classified as liabilities. The value of the amended Warrants was adjusted to the fair value immediately prior to the Warrant Amendments, resulting in a net gain of approximately $433,000 in the statement of operations, and approximately $3.3 million was reclassified from warrant liability to additional paid-in capital.

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

Stock-Based Compensation

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

In June 2019, 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, 2,456,999 stock options were exchanged for 1,842,746 replacement stock options. The replacement stock options have a four-year vesting schedule and an exercise price of $0.62 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 will recognize approximately $84,000 of additional stock-based compensation expense over the four-year vesting term of the exchanged options.

The estimated fair value of each stock option award granted was determined on the date of grant using the Black Scholes option-pricing valuation model with the following weighted-average assumptions for option grants during the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	**2018**
Common Stock Options		
Risk free interest rate	1.80% - 2.55%	2.66% - 2.85%
Expected option term	4.27 - 6.0 years	5.5 - 6.0 years
Expected volatility of common stock	90.34% - 112.58%	90.15% - 92.30%
Expected dividend yield	0.0%	0.0%

There were no stock options granted during the three months ended September 30, 2019 and 2018.

The estimated fair value of the shares to be acquired under the ESPP was determined on the initiation date of each six-month purchase period using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for ESPP shares to be purchased during the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Employee Stock Purchase Plan				
Risk free interest rate	1.89%	2.29%	1.89% - 2.52%	1.85% - 2.29%
Expected term	0.5 years	0.5 years	0.5 years	0.5 years
Expected volatility of common stock	170.68%	45.24%	130.36% - 170.68%	45.24% - 58.76%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 179,227	$ 161,515	$ 533,518	$ 519,025
General and administrative	152,076	218,547	521,585	642,241
Total stock-based compensation expense	$ 331,303	$ 380,062	$ 1,055,103	$ 1,161,266

As of September 30, 2019, there were approximately $2.4 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.

6. Commercial Services Agreement

On January 5, 2019, the Company entered into a commercial services agreement with NGP (the “NGP Agreement”) for the commercialization of Gimoti. Pursuant to the NGP Agreement, NGP will manage the commercial operations for a dedicated sales team to market Gimoti, if approved by FDA, to gastroenterologists and other targeted health care providers.

Under the terms of the NGP Agreement, the Company maintains ownership of the Gimoti NDA, as well as legal, regulatory, and manufacturing responsibilities for Gimoti. The Company will also retain a contract sales organization, which would be managed by NGP. The Company will record sales for Gimoti and retain more than 80% of product profits. NGP will receive a percentage of product profits in the mid-to-high teens as a service fee (such product profit amount, the “Contribution Profits”).

Pursuant to the NGP Agreement, upon any Gimoti NDA approval, NGP has agreed to finance the Company’s working capital requirements for specified commercialization costs in an amount by which Contribution Profits are expected to fall (or do actually fall) below zero (as projected by sales forecasts and a commercialization budget) to be drawn by the Company on a monthly basis, as needed (“NGP Working Capital Loan”), pursuant to a credit agreement to be negotiated in good faith between the Company and NGP (“NGP Credit Agreement”). The NGP Working Capital Loan will be repaid by the Company, if at all, only out of positive Contribution Profits, unless the NGP Agreement is terminated (a) by NGP due to a material breach by the Company, or (b) by the Company other than due to the gross negligence or intentional misconduct of NGP. Termination of the NGP Agreement by NGP for any other reason (including, without limitation, minimum net sales thresholds and negative Contribution Profits, as described below) will cause the NGP Working Capital Loan to be forgiven in full. The interest rate and other terms of the NGP Working Capital Loan will be set forth in the NGP Credit Agreement.

In addition, under the NGP Agreement, NGP has agreed to provide a line of credit of up to $5.0 million to the Company following NDA approval of Gimoti, if any, and for a period of up to nine months thereafter. The line of credit will be extended pursuant to a credit agreement between the parties. NGP will receive a low single digit percentage on net sales of Gimoti in lieu of any interest on the line of credit (the “NGP Credit Fee”); provided that in no event shall the cumulative NGP Credit Fee exceed twice the amount of the principal borrowed by the Company. The line of credit will mature on the earlier of 30 days following the date the NGP Credit Fee is twice the amount of the borrowed principal and the two-year anniversary of the date the principal is borrowed by the Company. In the event the Company secures financing from a third-party wholesale distributor for the purchase of Gimoti for launch in excess of $2.5 million dollars, NGP will no longer be required to offer the line of credit.

The term of the NGP Agreement is five years from the date of commercial launch of Gimoti, if any, after which the Company will recapture 100% of product sales and assume all corresponding responsibilities. Within 30 days after each one-year anniversary of the NGP Agreement, either party may terminate the NGP Agreement if net sales of Gimoti do not meet certain annual thresholds. Either party may terminate the NGP Agreement for the material breach of the other party, subject to a 60-day cure period, or in the event an insolvency petition of the other party is pending for more than 60 days. Either party may also terminate the NGP Agreement upon
30-days written notice to the other party if Gimoti is subject to a safety recall, the parties are unable to agree to a commercialization plan and budget by a specified date, or if the Contribution Profit is negative for any calendar quarter beginning with the first full calendar quarter nine months following commercial launch. In addition, NGP may terminate the NGP Agreement if the Company withdraws Gimoti from the market for more than 180 days or if the Company is unable to provide product samples for use by the salesforce in a timely manner. NGP may also terminate the NGP Agreement, including the obligation to provide a line of credit, since Gimoti was not approved by FDA by April 30, 2019, but, as of November 6, 2019, has not elected to do so. The Company may terminate the NGP Agreement upon a change of control of the Company, subject to a one-time payment equal to between four times and one times annualized service fees paid by the Company under the NGP Agreement, with such amount based on which year (between one and five years) after commercial launch the change of control occurs, provided if the change of control occurs within one year of commercial launch, such amount will be the greater of the specified annualized service fee amount and $5 million.

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, 2018 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 6, 2019. 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, such as the New Drug Application, or NDA, for Gimoti and our plans and expectations to address the issues raised in the Complete Response Letter, or CRL, received from U.S. Food and Drug Administration, or FDA, regulatory developments, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statement. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. As a result of many factors, including without limitation those set forth under "Risk Factors" under Item 1A of Part II below, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. Except as required by applicable law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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

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

Overview

We are a specialty pharmaceutical company focused primarily on the development of drugs to treat gastrointestinal, or GI, disorders and diseases. We are developing Gimoti, an investigational metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. Diabetic gastroparesis is a GI disorder afflicting millions of individuals 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 designed to provide systemic delivery of the molecule through the nasal mucosa. We submitted an NDA for Gimoti to FDA on June 1, 2018 and received a Day-74 FDA filing communication letter in August 2018. The letter stated that the NDA was sufficiently complete to permit a substantive review and set a target goal date under the Prescription Drug User Fee Act, or PDUFA, of April 1, 2019.

On March 1, 2019, we received a multi-disciplinary review letter, or DRL, from FDA, which provided preliminary notice of certain deficiencies identified during FDA's initial review of the Gimoti NDA. Specifically, the DRL described concerns with the information provided in the NDA that insufficient evidence had been offered regarding product quality control and reproducibility for the commercially available sprayer device used with Gimoti, that there is a lack of adequate information to support sex-based efficacy claims and that the pharmacology data provided may not demonstrate bioavailability to the Listed Drug, Reglan Tablets 10 mg. On March 14, 2019, we submitted a response to the DRL to FDA. In addition, on March 21, 2019, we had a meeting with FDA to obtain feedback on our responses.

On April 1, 2019, we received a CRL from FDA for our NDA. The CRL, which cited fewer issues than the DRL, stated that FDA has determined it cannot approve the NDA in its present form and provided recommendations to address the two remaining approvability issues in an NDA resubmission. The approvability issues are related to clinical pharmacology and product quality/device quality. FDA did not request any new clinical data and did not raise any safety concerns.

The clinical pharmacology issue was specific to a low maximum observed plasma concentration, or C_{max}, in subjects representing less than 5% of the total administered Gimoti doses in the pivotal pharmacokinetic, or PK, study. FDA stated the overall lower mean C_{max} was driven by the data from these few doses. Without the aberrant doses, our analysis shows the data met the bioequivalence criteria for both men and women, although there is no assurance that FDA will agree with our conclusion. FDA recommended a root cause analysis to determine the origin of the PK variability and mitigation strategies to address the issue. Additionally, FDA requested data from three registration batches of commercial product to be manufactured at the proposed commercial manufacturing site, by the proposed commercial process and tested using validated analytical methods. These data were requested to provide additional support for the proposed acceptance criteria for droplet size distribution and other essential performance characteristics for the commercial product specifications.

On July 25, 2019, we completed a type A meeting with FDA to obtain FDA's feedback and agreement on our plan to address deficiencies cited in the CRL in support of a resubmission of the Gimoti NDA. The focus of the discussion was on topics noted in the CRL, including the root cause analysis of low drug exposure in the comparative bioavailability study and additional product quality/device quality control testing.

Based on FDA feedback and the meeting minutes, we will include our root cause analysis and previously collected patient use and experience information in our resubmission package. We also agreed to provide an analysis of pump performance characteristics on the nasal spray devices used in the comparative bioavailability study and 3-month stability data from commercial scale batches of Gimoti which we initiated manufacturing in June 2019 and completed manufacturing in September 2019. No additional human clinical trials were requested by FDA. We plan to resubmit the Gimoti NDA in the fourth quarter of 2019.

On January 5, 2019, we entered into a commercial services agreement, or NGP Agreement, with Novos Growth, LLC, or NGP, for the commercialization of Gimoti. Pursuant to the NGP Agreement, NGP will manage the commercial operations for a dedicated sales team to market Gimoti, if approved by FDA, to gastroenterologists and other targeted health care providers.

Under the terms of the NGP Agreement, we maintain ownership of the Gimoti NDA, as well as legal, regulatory, and manufacturing responsibilities for Gimoti. We will also retain a contract sales organization, which would be managed by NGP. We will record sales for Gimoti and retain more than 80% of product profits. NGP will receive a percentage of product profits, or Contribution Profits, in the mid-to-high teens as a service fee. During the term of the NGP Agreement, NGP agrees to not commercialize a competing product in the United States other than pursuant to the NGP Agreement.

Pursuant to the NGP Agreement, upon any Gimoti NDA approval, NGP has agreed to finance our working capital requirements for specified commercialization costs in an amount by which Contribution Profits are expected to fall (or do actually fall) below zero (as projected by sales forecasts and a commercialization budget) to be drawn by us on a monthly basis, as needed, or NGP Working Capital Loan, pursuant to a credit agreement, to be negotiated in good faith between us and NGP, or NGP Credit Agreement. The NGP Working Capital Loan will be repaid by us, if at all, only out of positive Contribution Profits, unless the NGP Agreement is terminated (a) by NGP due to a material breach by us, or (b) by us other than due to the gross negligence or intentional misconduct of NGP. Termination of the NGP Agreement by NGP for any other reason (including, without limitation, minimum net sales thresholds and negative Contribution Profits, as described below) will cause the NGP Working Capital Loan to be forgiven in full. The interest rate and other terms of the NGP Working Capital Loan will be set forth in the NGP Credit Agreement.

In addition, under the NGP Agreement, NGP has agreed to provide a line of credit of up to $5.0 million to us following NDA approval of Gimoti, if any, and for a period of up to nine months thereafter. The line of credit will be extended pursuant to a credit agreement to be negotiated in good faith by the parties. NGP will receive a low single digit percentage on net sales of Gimoti, or NGP Credit Fee, in lieu of any interest on the line of credit; provided that in no event shall the cumulative NGP Credit Fee exceed twice the amount of the principal borrowed by us. The line of credit will mature on the earlier of 30 days following the date the NGP Credit Fee is twice the amount of the borrowed principal and the two-year anniversary of the date the principal is borrowed by us. In the event we secure financing from a third-party wholesale distributor for the purchase of Gimoti for launch in excess of $2.5 million dollars, NGP will no longer be required to offer the line of credit. NGP may terminate the NGP Agreement, including the obligation to provide a line of credit, since Gimoti was not approved by FDA by April 30, 2019, but, as of November 6, 2019, has not elected to do so.

We have no products approved for sale, and we have not generated any revenue from product sales or other arrangements. We have primarily funded our operations through the sale of our convertible preferred stock prior to our initial public offering in September 2013, borrowings under our bank loans and the sale of shares of our common stock on The Nasdaq Capital Market. We have incurred losses in each year since our inception. Substantially all of our operating losses resulted from expenses incurred in connection with advancing Gimoti through development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for at least the next several years. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

As of September 30, 2019, we had cash and cash equivalents of approximately $6.5 million. Current cash on hand is intended to fund interactions with FDA on the NDA resubmission for Gimoti, responding to approvability issues raised in the CRL received from FDA, and potentially manufacturing commercial batches of Gimoti. In addition, cash will be needed to fund pre-commercialization and pre-approval activities for Gimoti, including hiring a sales force, preparing for marketing and commercial manufacturing of Gimoti, and general and administrative costs to support 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 into the second quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the NGP Working Capital Loan and the NGP Credit Agreement. Under either situation, we will be required to raise additional funds in order to continue as a going concern. There can be no assurance that we will be able to further develop Gimoti, if required, and resubmit and receive FDA approval of the Gimoti NDA. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, 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 a complete loss of your investment in our securities.

Technology Acquisition Agreement

In June 2007, we acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor Pharmaceuticals, Inc., or Questcor, pursuant to an asset purchase agreement. We paid Questcor $650,000 in the form of an upfront payment and $500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in our Phase 3 clinical trial for Gimoti. In August 2014, Mallinckrodt, plc, or Mallinckrodt, acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the asset purchase agreement with us to Mallinckrodt. In addition to the payments previously made to Questcor, we may be required to make additional milestone payments totaling up to $52 million. In March 2018, we amended the asset purchase agreement with Mallinckrodt to defer development and approval milestone payments, such that rather than paying two milestone payments based on FDA acceptance for review of the NDA and final product marketing approval, we would be required to make a single $5 million payment one year after we receive FDA approval to market Gimoti.

The remaining $47 million in milestone payments depend on Gimoti's commercial success and will only apply if Gimoti receives regulatory approval. In addition, we will be required to pay Mallinckrodt a low single digit royalty on net sales of Gimoti. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2032.

Financial Operations Overview

Research and Development Expenses

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

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

All of our research and development expenses to date have been incurred in connection with the development of Gimoti. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. While we plan to resubmit the NDA in the fourth quarter of 2019, the successful development and commercialization of Gimoti is still highly uncertain, in part due to our receipt of the CRL from FDA. We are unable to estimate with any certainty the costs we will incur in the continued development and regulatory review of Gimoti, though such costs may be significant. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We may never succeed in achieving marketing approval for our product candidate.

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

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects;
- the number of subjects that participate in the trials;

- the number of doses that subjects receive;
- the cost of comparative agents used in trials;
- the drop-out or discontinuation rates of subjects;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

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

General and Administrative Expenses

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

Other Income

Other income consists primarily of changes in the fair value of the warrant liability, which represents the change in the fair value of common stock warrants from the date of issuance to the end of the reporting period. The warrant liability was revalued each reporting period until March 2018, when we entered into warrant amendments, or the Warrant Amendments, with each of the holders of our outstanding warrants to purchase common stock issued on July 25, 2016 and August 3, 2016, or the Warrants. We previously used the Black Scholes valuation model to value the related warrant liability at each reporting date. As a result of the Warrant Amendments, the Warrants are no longer required to be accounted for as a liability and are no longer required to be revalued at each reporting period.

Critical Accounting Policies and Significant Judgments and Estimates

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

The critical accounting policies and estimates underlying the accompanying unaudited financial statements are those set forth in Part II, Item 7 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the SEC on March 6, 2019.

Other Information

None.

Results of Operations

Comparison of Three Months Ended September 30, 2019 and 2018

The following table summarizes the results of our operations for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Increase/
	2019	2018	(Decrease)
Research and development expenses	$ 822,444	$ 625,497	$ 196,947
General and administrative expenses	$ 814,218	$ 897,060	$ (82,842)

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2019 compared to the three months ended September 30, 2018 increased by approximately $197,000. During 2019, we incurred expenses primarily related to responding to requests for additional information from FDA for the Gimoti NDA and manufacturing registration batches of Gimoti, while in 2018 we incurred expenses primarily related to responding to requests for additional information from FDA for the Gimoti NDA. Costs incurred in 2019 included approximately $493,000 for wages, taxes and employee insurance, including approximately $179,000 of stock-based compensation expense, approximately $248,000 related to manufacturing, and approximately $75,000 related to responding to the CRL from FDA and preparing for the NDA resubmission. Costs incurred in 2018 included approximately $566,000 for wages, taxes and employee insurance, including approximately $162,000 of stock-based compensation expense.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2019 compared to the three months ended September 30, 2018 decreased by approximately $83,000. Costs incurred in 2019 primarily included approximately $423,000 for wages, taxes and employee insurance, including approximately $152,000 of stock-based compensation expense, and approximately $326,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. Costs incurred in 2018 primarily included approximately $502,000 for wages, taxes and employee insurance, including approximately $219,000 of stock-based compensation expense, and approximately $299,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

Comparison of Nine Months Ended September 30, 2019 and 2018

The following table summarizes the results of our operations for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,		Increase/
	2019	**2018**	**(Decrease)**
Research and development expenses	$ 2,774,924	$ 3,399,654	$ (624,730)
General and administrative expenses	$ 2,955,371	$ 2,846,611	$ 108,760
Other (income)	$ (22,868)	$ (440,817)	$ (417,949)

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018 decreased by approximately $625,000. During 2019, we incurred expenses primarily related to responding to requests for additional information from FDA and manufacturing registration batches of Gimoti, while in 2018 we incurred expenses primarily related to preparing the Gimoti NDA. Costs incurred in 2019 included approximately $1.8 million for wages, taxes and employee insurance, including approximately $534,000 of stock-based compensation expense, approximately $787,000 related to manufacturing, and approximately $150,000 related to responding to the CRL from FDA and preparing for the NDA resubmission. Costs incurred in 2018 included approximately $1.9 million for wages, taxes and employee insurance, including approximately $519,000 of stock-based compensation expense, approximately $1.2 million related to the preparation of the NDA and responding to requests for additional information from FDA related to the NDA, and approximately $329,000 related to manufacturing costs.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018 increased by approximately $109,000. Costs incurred in 2019 primarily included approximately $1.4 million for wages, taxes and employee insurance, including approximately $522,000 of stock-based compensation expense, approximately $1.2 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company, approximately $116,000 for outside consultants, and approximately $68,000 for pre-commercialization costs. Costs incurred in 2018 primarily included approximately $1.4 million for wages, taxes and employee insurance, including approximately $642,000 of stock-based compensation expense, and approximately $1.1 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

Other Income. Other income for the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018 decreased by approximately $418,000 due primarily to no longer being required to revalue the Warrants. Since the date of the Warrant Amendments in March 2018, the Warrants are no longer classified as a liability on our balance sheet, were adjusted to fair value and were reclassified to additional paid-in capital, a component of stockholders' equity. Prior to the amendment, the Warrants were accounted for as a liability and were required to be revalued at each reporting period.

Liquidity and Capital Resources

In November 2017, we filed a shelf registration with the SEC on Form S-3. The 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 FBR, Inc., or FBR, as a sales agent, or FBR Sales Agreement. During the year ended December 31, 2018, we sold 1,985,054 shares of common stock

at a weighted-average price per share of $2.38 pursuant to the FBR Sales Agreement and received proceeds of approximately $4.6 million, net of commissions and fees. During the nine months ended September 30, 2019, we sold 6,804,381 shares of common stock at a weighted-average price per share of $0.87 pursuant to the FBR Sales Agreement and received proceeds of approximately $5.8 million, net of commissions and fees. As of September 30, 2019, we had approximately $5.4 million remaining to sell under this Form S-3.

Under current SEC regulations, if at the time we file our Annual Report on Form 10-K ("Form 10-K"), and our public float is less than $75 million, and for so long as our public float remains less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float, which is referred to as the baby shelf rules. As of October 31, 2019, our public float was approximately $21.0 million, based on 21,194,539 shares of outstanding common stock held by non-affiliates at a price of $0.99 per share, which was the last reported sale price of our common stock on The Nasdaq Capital Market on September 17, 2019. As a result of our public float being below $75 million, we will be limited by the baby shelf rules until such time as our public float exceeds $75 million, which means we only have the capacity to sell shares up to one-third of our public float under shelf registration statements in any twelve-month period. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease. As of October 31, 2019, we had the capacity to issue up to approximately $1.1 million of additional shares of common stock pursuant to the FBR Sales Agreement.

Future sales under the FBR Sales Agreement will depend on a variety of factors including, but not limited to, market conditions, the trading price of our common stock and our capital needs. There can be no assurance that FBR will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate.

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

In March 2018, we entered into the Warrant Amendments with each of the holders of our outstanding Warrants acquired as part of our financings which closed in July and August 2016. As a result of the Warrant Amendments, all of the remaining Warrants to purchase 2,449,129 shares of our common stock are no longer required to be classified as liabilities. The value of the amended Warrants was adjusted to the fair value immediately prior to the Warrant Amendments, resulting in a gain of approximately $433,000 in the statement of operations, and approximately $3.3 million was reclassified from warrant liability to additional paid-in capital, a component of stockholders' equity.

Management concluded that there is substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm also included an explanatory paragraph in their report on our financial statements as of and for the year ended December 31, 2018 with respect to our ability to continue as a going concern. This doubt about our ability to continue as a going concern for at least twelve months from the date of the financial statements 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. We believe, based on our current operating plan, that our existing cash and cash equivalents will be sufficient to fund our operations into the second quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the NGP Working Capital Loan and the NGP Credit Agreement. Under either situation, we will be required to raise additional funds in order to continue as a going concern. There can be no assurance that we will be able to further develop Gimoti, if required, and resubmit and receive FDA approval of the Gimoti NDA. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, 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 a complete loss of your investment in our securities.

These estimates of cash runway could be shortened if there are any significant increases in planned spending on responding to the issues raised by FDA in the CRL, pre-commercialization and pre-approval activities, including hiring a sales force, preparing for marketing and manufacturing of Gimoti, and our general and administrative costs to support operations. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

On May 15, 2019, we received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on The Nasdaq Capital Market.

In accordance with Nasdaq listing rules, we have been provided an initial period of 180 calendar days, or until November 11, 2019, to regain compliance. The letter states that Nasdaq will provide written notification that we have achieved compliance with its rules if at any time before November 11, 2019, the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. The Nasdaq letter has no immediate effect on the listing or trading of our common stock and the common stock will continue to trade on The Nasdaq Capital Market.

We do not expect to regain compliance with Nasdaq listing rules by November 11, 2019, but we may be eligible for an additional 180 calendar day compliance period. To qualify, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. We intend to provide such notice prior to the expiration of the initial compliance period and as of the date of this report we meet the continued requirements, other than the bid price requirement. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq would notify us that our securities would be subject to delisting. In the event of such a notification, we may appeal Nasdaq's determination to delist our securities, but there can be no assurance Nasdaq would grant our request for continued listing.

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:

- respond to the issues raised in the CRL, conduct additional development activities, if required, and prepare an NDA resubmission;
- continue the pre-approval and pre-commercialization activities for Gimoti;
- continue the preparation of the commercial manufacturing process;
- maintain, expand and protect our intellectual property portfolio; and
- continue to fund the additional accounting, legal, insurance and other costs associated with being a public company.

The following table summarizes our cash flows for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,		Increase/
	2019	2018	(Decrease)
Net cash used in operating activities	$ (4,614,403)	$ (5,729,646)	$ (1,115,243)
Net cash provided by financing activities	$ 5,800,201	$ 4,618,297	$ 1,181,904
Net increase (decrease) in cash and cash equivalents	$ 1,185,798	$ (1,111,349)	$ 2,297,147

Operating Activities. The primary use of our cash has been to fund our clinical research, the preparation of our NDA, manufacture of Gimoti, and other general operations. The cash used in operating activities during the nine months ended September 30, 2019 was primarily related to ongoing communication with FDA related to the NDA and the CRL, and to manufacture registration batches of Gimoti. The cash used in operating activities during the nine months ended September 30, 2018 was primarily related to the preparation of the NDA and responding to FDA questions related to the NDA. We expect that cash used in operating activities during the next year will continue to be used to respond to the CRL, resubmit the NDA to FDA, and work on pre-approval and pre-commercialization activities, as well as commercialization activities, should FDA approve the NDA for Gimoti.

Financing Activities. During the nine months ended September 30, 2019, we received net proceeds of approximately $5.8 million from the sale of 6,804,381 shares of common stock pursuant to the FBR Sales Agreement. During the nine months ended September 30, 2018, we received net proceeds of approximately $4.6 million from the sale of 1,985,054 shares of common stock pursuant to the FBR Sales Agreement.

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, including to address the issues raised by FDA in the CRL and to resubmit the NDA;
- we may not be able to provide acceptable evidence of safety and efficacy for Gimoti;
- we may be required to undertake additional clinical trials and other studies of Gimoti before we receive approval of the NDA if and when it is resubmitted;
- FDA may disagree with the design of our future clinical trials, if any are necessary;

- FDA may not agree with the analysis of our clinical trial results;
- the results of our clinical trials may not meet the level of statistical or clinical significance or other bioequivalence parameters required by FDA for marketing approval;
- subjects in our clinical trials may die or suffer other adverse effects for reasons that may or may not be related to Gimoti, such as dysgeusia, headache, diarrhea, nasal discomfort, tremor, myoclonus, somnolence, rhinorrhea, throat irritation, and fatigue;
- contract manufacturers, suppliers and/or consultants may not meet appropriate timelines;
- if approved, Gimoti will compete with well-established products already approved for marketing by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights; and
- we may not be able to establish commercial-scale manufacturing capabilities.

Off-Balance Sheet Arrangements

Through September 30, 2019, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

Contractual Obligations and Commitments

There were no material changes outside the ordinary course of our business during the nine months ended September 30, 2019 to the information regarding our contractual obligations that was disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 6, 2019.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

As of September 30, 2019, 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, 2018, filed with the SEC on March 6, 2019.

Item 4. Controls and Procedures

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Business Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Business Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Business Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2019.

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, 2018, filed with the SEC on March 6, 2019, other than as set forth below:

Risks Related to our Business, including the Development, Regulatory Approval and Potential Commercialization of our Product Candidate, Gimoti

Our business is entirely dependent on the success of Gimoti, which 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 received a CRL from FDA for our Gimoti NDA and we cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, Gimoti.

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

In December 2016, we announced the completion of a pre-NDA meeting with FDA, in which FDA agreed that a comparative exposure PK trial was acceptable as a basis for submission of a Gimoti NDA. Data from the comparative exposure PK trial will serve as a portion of the 505(b)(2) data package to include prior efficacy and safety data developed by us and FDA's prior findings of safety and efficacy for the Listed Drug, Reglan Tablets 10 mg. In October 2017, we announced positive topline results from the comparative exposure PK trial. In addition, based on feedback received from FDA at an additional pre-NDA meeting, we proposed a risk mitigation strategy and post-approval safety trial as part of the NDA we submitted for Gimoti to FDA on June 1, 2018. We received a Day-74 filing communication letter in August 2018 that stated that the NDA was sufficiently complete to permit a substantive review and set a target goal date under PDUFA of April 1, 2019. On March 1, 2019, we received a DRL from FDA, which provided preliminary notice of certain deficiencies identified during FDA's initial review of the Gimoti NDA. Specifically, the DRL described concerns with the information provided in the NDA, including concerns that insufficient evidence had been offered regarding product quality control and reproducibility specific to the commercially available sprayer device used with Gimoti, that there is a lack of adequate information to support sex-based efficacy claims and that the pharmacology data provided may not demonstrate bioavailability to the Listed Drug, Reglan Tablets 10 mg.

On April 1, 2019, we received a CRL from FDA for our NDA. The CRL stated that FDA determined it could not approve the NDA in its present form and provided recommendations to address the two remaining approvability issues in an NDA resubmission. The approvability issues are related to clinical pharmacology and product quality/device quality. FDA did not request any new clinical data and did not raise any safety concerns.

The clinical pharmacology issue was specific to a low C_{max} in subjects representing less than 5% of the total administered Gimoti doses in the pivotal PK study. FDA stated the overall lower mean C_{max} was driven by the data from these few doses. Without the aberrant doses, our analysis shows the data met the bioequivalence criteria for both men and women, although there is no assurance that FDA will agree with our conclusion. FDA recommended a root cause analysis to determine the origin of the PK variability and mitigation strategies to address the issue. Additionally, FDA requested data from three registration batches of commercial product to be manufactured at the proposed commercial manufacturing site, by the proposed commercial process and tested using validated analytical methods These data were requested to provide additional support for the proposed acceptance criteria for droplet size distribution and other essential performance characteristics for the commercial product specifications.

On July 25, 2019, we completed a type A meeting with FDA to obtain FDA's feedback and agreement on our plan to address deficiencies cited in the CRL in support of a resubmission of the Gimoti NDA. The focus of the discussion was on topics noted in the CRL, including the root cause analysis of low drug exposure in the comparative bioavailability study and additional product quality/device quality control testing.

Based on FDA feedback and the meeting minutes, we will include our root cause analysis and previously collected patient use and experience information in our resubmission package. We also agreed to provide an analysis of pump performance characteristics on the nasal spray devices used in the comparative bioavailability study and 3-month stability data from commercial scale batches of Gimoti which we initiated manufacturing in June 2019 and completed manufacturing in September 2019. No additional human clinical trials were requested by FDA. We plan to resubmit the Gimoti NDA in the fourth quarter of 2019. However, FDA may determine that our

root cause analysis and additional patient data and/or the stability data do not adequately address the issues raised in the CRL, or support approval of the NDA, and may later require us to conduct additional human clinical trials prior to approval. In addition, FDA may not accept our planned NDA resubmission for review.

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 be able to provide acceptable evidence of safety and efficacy for Gimoti, including as a result of the proposed duration of use for Gimoti being shorter as compared to the maximum approved dosing duration for the referenced Listed Drug, Reglan Tablets 10 mg.;
- the results of our clinical trials may not meet the level of statistical or clinical significance or other bioequivalence parameters required by FDA for marketing approval, including C_{max} falling below the equivalence range in the comparative exposure PK trial;
- FDA may not agree with the analysis of our clinical trial results, including our analysis of results of the PK trial;
- later developments with FDA that may be inconsistent with our recent type A meeting;
- we may be required to undertake additional clinical trials and other studies of Gimoti before we receive approval of the NDA if and when it is resubmitted;
- we may not have sufficient financial and other resources to complete clinical development for Gimoti;
- 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;
- our reliance on NGP and any third-party sales organization to commercialize Gimoti, if approved;
- we may not be able to maintain commercial manufacturing arrangements with third-party manufacturers or establish and maintain commercial-scale manufacturing capabilities;
- contract manufacturers, suppliers and/or consultants may not meet appropriate timelines;
- FDA may disagree with the design of any future clinical trials, if any are necessary;
- 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; and
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights.

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 may 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 into the second quarter of 2020. Following our planned resubmission of the Gimoti NDA, and assuming the FDA accepts the NDA for review, the FDA will set a target goal date to respond to the Gimoti NDA under PDUFA, which date could be either two or six months from the date of our resubmission. Accordingly, we may not have sufficient liquidity to fund our operations through the PDUFA date and we cannot provide any assurance that we will be able to raise additional funds on acceptable terms, or at all. If Gimoti is approved by FDA, additional funds will become available from the NGP Working Capital Loan and the NGP Credit Agreement. Under either situation, we will be required to raise additional funds in order to continue as a going concern. There can be no assurance that we will be able to raise additional funds to further develop Gimoti, if required, and resubmit and receive FDA approval of the Gimoti NDA. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, 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 a complete loss of your investment in our securities.

Our estimates of the amount of cash necessary to fund our activities may prove to be wrong and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the need for, and the progress, costs and results of, any additional clinical trials of Gimoti that may be required by FDA, including any pre-approval or post-approval trials FDA or other regulatory agencies may require evaluating the efficacy or safety of Gimoti;
- the costs involved for additional data collection and analysis to respond to FDA questions related to the NDA and to respond to the CRL and resubmit the NDA;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from FDA, and any similar regulatory agencies;
- the costs and timing of completion of outsourced commercial manufacturing supply arrangements for Gimoti;
- the costs required to commercialize Gimoti, including expenses incurred under our commercialization agreement with NGP, and the costs of establishing or outsourcing additional sales, marketing and distribution capabilities;
- the commercial success of Gimoti, if approved;
- 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, resubmit the NDA or to otherwise survive as a going concern.

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

We submitted an NDA for Gimoti in June 2018. Under PDUFA, FDA is subject to a two-tiered system of review times - Standard Review and Priority Review. For drugs subject to standard review, such as Gimoti, FDA has a goal to complete its review of the NDA and respond to the applicant within ten months from the date of receipt of an NDA. In its Day-74 filing communication letter, FDA assigned a target goal date under PDUFA of April 1, 2019 for the Gimoti NDA. On April 1, 2019, we received a CRL from FDA for our NDA. The CRL stated that FDA could not approve the NDA in its present form and provided recommendations to address the remaining approvability issues in an NDA resubmission.

On July 25, 2019, we completed a type A meeting with FDA to obtain FDA's feedback and agreement on our plan to address deficiencies cited in the CRL in support of a resubmission of the Gimoti NDA. The focus of the discussion was on topics noted in the CRL, including the root cause analysis of low drug exposure in the comparative bioavailability study and additional product quality/device quality control testing.

Based on FDA feedback and the meeting minutes, we will include our root cause analysis and previously collected patient use and experience information in our resubmission. We also agreed to provide an analysis of pump performance characteristics on the nasal spray devices used in the comparative bioavailability study and 3-month stability data from commercial scale batches of Gimoti which we initiated manufacturing in June 2019 and completed manufacturing in September 2019. No additional human clinical trials were requested by FDA. We are currently completing the stability analysis from the commercial scale batches as well as undertaking the testing of pump performance characteristics on the nasal spray devices as requested by FDA. We plan to resubmit the Gimoti NDA in the fourth quarter of 2019, but we cannot assure you that we will complete our ongoing analyses, or that results will be in line with our expectations, in order to resubmit the NDA on this timeframe. In addition, FDA may determine that our root cause analysis and additional patient data and/or the stability data do not adequately address the issues raised in the CRL, or support approval of the NDA, and may later require us to conduct additional human clinical trials prior to approval. In addition, FDA may not accept our planned NDA resubmission for review.

The duration of FDA's review of any resubmitted NDA may depend on the number and type of other NDAs that are submitted with FDA around the same time period. In addition, FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the

application should be approved and under what conditions. FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions.

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

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

We have no internal sales, marketing or distribution capabilities currently and will rely on NGP and other third parties for the commercialization of Gimoti, and we and they may not be able to effectively market, sell and distribute Gimoti, if approved.

Currently, we have no internal sales, marketing or distribution capabilities. If Gimoti ultimately receives regulatory approval, we may not be able to effectively market and distribute the product candidate. We have engaged NGP to manage the commercial operations for a dedicated sales team to market Gimoti. We anticipate engaging a third-party sales organization to retain, train and deploy this direct sales force. We may not be able to hire consultants or external service providers to assist us in retaining, training and deploying a sales force or for other sales, marketing and distribution functions on acceptable financial terms or at all. If we fail to engage with a third party on acceptable terms or at all, we will have to invest significant amounts of financial and management resource to develop internal sales, distribution and marketing capabilities. We have no experience in retaining, training or deploying a sales force and no experience in managing third-party sales organizations. Further, we or the third-party sales organization may be unable to identify and retain suitable candidates to fill our direct sales force needs, on our expected launch timeframe or otherwise. To the extent we or the third-party sales organization are not successful in retaining qualified sales and marketing personnel, we may not be able to effectively market Gimoti. Further, there can be no assurance that the capabilities of the NGP and the third-party sales organizations will effective in marketing and selling Gimoti, or that their personnel will be more effective than an internally developed sales organization. In addition, NGP may terminate our agreement, including the obligation to provide a line of credit, since Gimoti was not approved by FDA by April 30, 2019, but as of November 6, 2019, has not elected to do so, and can terminate the agreement under certain additional circumstances, including failure to make payments when due, if we are in material breach of the agreement and fail to remedy the breach following notice, if we enter into bankruptcy, or if we are excluded from participation in certain federal governmental programs or have similar actions taken against us. If we, or either NGP or the third-party sales organization, fails to hire, train, retain and manage qualified sales personnel, market our product successfully or on a cost-effective basis or otherwise terminates our relationship, our ability to generate revenue will be limited and we will need to identify and retain an alternative organization, or develop our own sales and marketing capability. In such an event, we would have to invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities. This could involve significant delays and costs, including the diversion of our management's attention from other activities. We may also need to retain additional consultants or external service providers to assist us in sales, marketing and distribution functions, and may be unsuccessful in retaining such services on acceptable financial terms or at all.

If we do perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- inability to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenues generated by Gimoti or any other product candidates that we may develop, in-license or acquire; and
- our direct sales and marketing efforts may not be successful.

If we are unsuccessful in building and managing a sales and marketing infrastructure internally or through a third-party partner for any approved product, we will have difficulty commercializing the product, which would adversely affect our business and financial condition.

Risks Related to Our Financial Position and Need for Capital

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, management concluded that there is substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm also included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2018 with respect to this uncertainty. This doubt about our ability to continue as a going concern could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. In addition, 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. 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.

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 into the second quarter of 2020. If Gimoti is approved by FDA, additional funds will become available from the NGP Working Capital Loan and the NGP Credit Agreement. This period could be shortened if there are any significant increases in planned spending on our Gimoti development program than anticipated. Under either situation, we will be required to raise additional funds in order to continue as a going concern. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. There can be no assurance that we will be able to further develop Gimoti, if required. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing or identify and execute on other development or strategic alternatives for Gimoti or our company, 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 a complete loss of your investment in our securities.

If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop and commercialize Gimoti.

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

- the need for, and the progress, costs and results of, any additional clinical trials of Gimoti required by FDA, including any additional trials FDA or other regulatory agencies may require evaluating the safety of Gimoti;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from FDA, and any similar regulatory agencies;
- the timing and costs associated with manufacturing Gimoti for clinical trials and other studies and, if approved, for commercial sale;
- our need and ability to hire additional management, development and scientific personnel;
- the cost to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the timing and costs associated with establishing sales and marketing capabilities;
- market acceptance of Gimoti;
- the extent to which we are required to pay milestone or other payments under our Mallinckrodt asset purchase agreement and the timing of such payments;

- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

Some of these factors are outside of our control. We cannot provide any assurance that our existing capital will be sufficient to enable us to fund any additional clinical development required for Gimoti, and, in any event, we will need to raise additional capital to complete such clinical development, as well as to prepare to commercialize Gimoti should we receive product approval. We may need to raise additional funds in the near future for commercialization for Gimoti.

We may seek additional funding through collaboration agreements, public or private equity financings, debt financings or receivables financings. For example, we currently may sell from time to time, at our option, up to an aggregate of $16.0 million of shares of our common stock through FBR, as sales agent pursuant to the FBR Sales Agreement. Sales pursuant to the FBR Sales Agreement are registered pursuant to a shelf registration statement on Form S-3 which was declared effective by the SEC on December 28, 2017. As of October 31, 2019, we had sold approximately $10.6 million of shares of our common stock pursuant to the FBR Sales Agreement. However, 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 October 31, 2019, our public float was approximately $21.0 million which means we may only sell approximately $1.1 million of securities using our shelf registration statements. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease. In addition, 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.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline and dilute the holdings of our existing stockholders. If we 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.

If we are unable to obtain funding on a timely basis, if required, we will be unable to complete additional clinical development of Gimoti and may be required to significantly curtail all of our activities. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to our product candidate or some of our technologies or otherwise agree to terms unfavorable to us.

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

Our common stock is listed on The Nasdaq Capital Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum closing bid price per share of $1.00 and continued business operations so that we are not characterized as a "public shell company." On May 15, 2019, we received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on The Nasdaq Capital Market. Although Nasdaq provided us with a 180-calendar day compliance period in which to regain compliance with the minimum closing bid price requirement, we cannot assure you that we will be able to regain compliance within the period provided by Nasdaq. The letter states that Nasdaq will provide written notification that we have achieved compliance with its rules if at any time before November 11, 2019, the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days during the compliance period. We do not expect to regain compliance with the Nasdaq listing rules by November 11, 2019, but we may be eligible for an additional 180 calendar day compliance period. To qualify, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement as of November 11, 2019, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. We intend to provide such notice prior to the expiration of the initial compliance period and as the date of this report we meet the continued listing requirements, other than the bid price requirement. However, we cannot assure you that we will meet the requirements for continued listing, other than the bid price requirement, as of November 11, 2019 and Nasdaq may deny our request for an additional compliance period. If Nasdaq denies our request for an additional compliance period or we are not able to regain compliance within any additional compliance period for this requirement or any other applicable listing standard, our shares of common stock would be subject to delisting. In the event that our common stock is delisted from The Nasdaq Capital Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board.

In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

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

Unregistered Sales of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Index to Exhibits

Exhibit Number	Description of Exhibit
3.1 (1)	Amended and Restated Certificate of Incorporation of the Company
3.2 (1)	Amended and Restated Bylaws of the Company
4.1 (2)	Form of the Company's Common Stock Certificate
4.2 (3)	Investor Rights Agreement dated as of June 1, 2007
4.3 (3)	Warrant dated June 1, 2012 issued by the Company to Silicon Valley Bank
4.4 (4)	Form of Warrant issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated July 25, 2016
4.5 (5)	Form of Warrant issued by the Company to certain investors under the Securities Purchase Agreement between the Company and such investors dated August 3, 2016
4.6 (6)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
4.7 (7)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
4.8 (8)	Form of Amendment to Common Stock Purchase Warrant, amending certain of the warrants dated July 25, 2016 and August 3, 2016
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on September 30, 2013.
(2) Incorporated by reference to the Company's Amendment No. 3 to Registration Statement on Form S-1 filed with the SEC on August 16, 2013.
(3) Incorporated by reference to the Company's Registration Statement on Form S-1 filed with the SEC on May 24, 2013.
(4) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on July 20, 2016.
(5) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2016.
(6) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on December 16, 2016
(7) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on March 23, 2018
(8) Incorporated by reference to the Company's Current Report on Form 8-K filed with the SEC on April 4, 2018
* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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

Evoke Pharma, Inc.

Date: November 7, 2019

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

Date: November 7, 2019

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

Exhibit 31.1

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

I, David A. Gonyer, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2019

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

Exhibit 31.2

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2019

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

Exhibit 32.1

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

In connection with the quarterly report of Evoke Pharma, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David A. Gonyer, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: November 7, 2019

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

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

Exhibit 32.2

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

In connection with the quarterly report of Evoke Pharma, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew J. D'Onofrio, Executive Vice President, Chief Business Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: November 7, 2019

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

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