

**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 June 30, 2020

OR

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

Commission File Number 001-36075

EVOKE PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

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

20-8447886
(IRS Employer
Identification No.)

92075
(Zip Code)

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

Title of each class
Common Stock,
par value \$0.0001 per share

Trading symbol
EVOK

Name of each exchange on which registered
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 July 31, 2020, the registrant had 26,011,263 shares of common stock outstanding.

<u>PART I. FINANCIAL INFORMATION</u>	1
<u>Item 1. Financial Statements</u>	1
<u>Condensed Balance Sheets as of June 30, 2020 (Unaudited) and December 31, 2019</u>	1
<u>Condensed Statements of Operations for the three and six months ended June 30, 2020 and 2019 (Unaudited)</u>	2
<u>Condensed Statements of Stockholders' Equity for the three and six months ended June 30, 2020 and 2019 (Unaudited)</u>	3
<u>Condensed Statements of Cash Flows for the six months ended June 30, 2020 and 2019 (Unaudited)</u>	4
<u>Notes to Condensed Financial Statements (Unaudited)</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	16
<u>Item 4. Controls and Procedures</u>	16
<u>PART II. OTHER INFORMATION</u>	17
<u>Item 1. Legal Proceedings</u>	17
<u>Item 1A. Risk Factors</u>	17
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	20
<u>Item 3. Defaults Upon Senior Securities</u>	20
<u>Item 4. Mine Safety Disclosure</u>	20
<u>Item 5. Other Information</u>	20
<u>Item 6. Exhibits</u>	21
<u>SIGNATURES</u>	23

PART I. FINANCIAL INFORMATION**Item 1. Financial Statements****Evoke Pharma, Inc.
Condensed Balance Sheets**

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 7,990,392	\$ 5,663,833
Prepaid expenses	193,902	581,706
Other current assets	11,551	—
Total current assets	<u>8,195,845</u>	<u>6,245,539</u>
Operating lease right-of-use asset	71,211	138,538
Other assets	—	11,551
Total assets	<u>\$ 8,267,056</u>	<u>\$ 6,395,628</u>
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 604,832	\$ 1,033,383
Accrued compensation	860,521	843,162
Operating lease liability	71,211	138,538
Paycheck protection program loan	104,168	—
Milestone payable	5,000,000	—
Total current liabilities	<u>6,640,732</u>	<u>2,015,083</u>
Long-term Liabilities:		
Note payable	<u>2,000,000</u>	<u>—</u>
Total liabilities	<u>8,640,732</u>	<u>2,015,083</u>
Stockholders' equity:		
Common stock, \$0.0001 par value; authorized shares - 50,000,000; issued and outstanding shares - 26,011,263 and 24,431,914 at June 30, 2020 and December 31, 2019, respectively	2,601	2,443
Additional paid-in capital	94,111,817	90,108,492
Accumulated deficit	<u>(94,488,094)</u>	<u>(85,730,390)</u>
Total stockholders' equity (deficit)	<u>(373,676)</u>	<u>4,380,545</u>
Total liabilities and stockholders' equity	<u>\$ 8,267,056</u>	<u>\$ 6,395,628</u>

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 5,782,094	\$ 1,205,599	\$ 6,245,946	\$ 1,952,481
General and administrative	1,182,872	918,139	2,512,707	2,141,152
Total operating expenses	<u>6,964,966</u>	<u>2,123,738</u>	<u>8,758,653</u>	<u>4,093,633</u>
Loss from operations	(6,964,966)	(2,123,738)	(8,758,653)	(4,093,633)
Other income (expense):				
Interest income	485	9,642	3,863	14,271
Interest expense	(2,914)	—	(2,914)	—
Total other income (expense)	<u>(2,429)</u>	<u>9,642</u>	<u>949</u>	<u>14,271</u>
Net loss	<u>\$ (6,967,395)</u>	<u>\$ (2,114,096)</u>	<u>\$ (8,757,704)</u>	<u>\$ (4,079,362)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.28)</u>	<u>\$ (0.09)</u>	<u>\$ (0.35)</u>	<u>\$ (0.20)</u>
Weighted-average shares used to compute basic and diluted net loss per share	<u>24,987,975</u>	<u>23,258,567</u>	<u>24,713,928</u>	<u>20,371,442</u>

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.
Condensed Statements of Stockholders' Equity
(Unaudited)

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-In Capital	Deficit	Stockholders' Equity (Deficit)
Balance at January 1, 2020	24,431,914	\$ 2,443	\$ 90,108,492	\$ (85,730,390)	\$ 4,380,545
Stock-based compensation expense	—	—	310,162	—	310,162
Issuance of common stock from employee stock purchase plan	25,000	3	21,247	—	21,250
Net loss	—	—	—	(1,790,309)	(1,790,309)
Balance at March 31, 2020	24,456,914	2,446	90,439,901	(87,520,699)	2,921,648
Stock-based compensation expense	—	—	362,955	—	362,955
Issuance of common stock from At-The-Market offering, net	1,395,855	140	3,308,976	—	3,309,116
Issuance of common stock from warrant exercises	158,494	15	(15)	—	—
Net loss	—	—	—	(6,967,395)	(6,967,395)
Balance at June 30, 2020	<u>26,011,263</u>	<u>\$ 2,601</u>	<u>\$ 94,111,817</u>	<u>\$ (94,488,094)</u>	<u>\$ (373,676)</u>

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-In Capital	Deficit	Stockholders' 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	<u>24,113,956</u>	<u>\$ 2,411</u>	<u>\$ 89,027,832</u>	<u>\$ (82,684,097)</u>	<u>\$ 6,346,146</u>

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.
Condensed Statements of Cash Flows
(Unaudited)

	Six Months Ended	
	June 30,	
	2020	2019
Operating activities		
Net loss	\$ (8,757,704)	\$ (4,079,362)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	673,117	723,800
Milestone expense	5,000,000	—
Change in operating assets and liabilities:		
Prepaid expenses and other assets	455,131	285,496
Accounts payable and other current liabilities	(478,519)	(485,247)
Net cash used in operating activities	(3,107,975)	(3,555,313)
Financing activities		
Proceeds from issuance of common stock, net	3,330,366	5,676,388
Proceeds from paycheck protection program	104,168	—
Proceeds from Eversana line of credit	2,000,000	—
Net cash provided by financing activities	5,434,534	5,676,388
Net increase in cash and cash equivalents	2,326,559	2,121,075
Cash and cash equivalents at beginning of period	5,663,833	5,319,004
Cash and cash equivalents at end of period	\$ 7,990,392	\$ 7,440,079

See accompanying notes to these unaudited condensed financial statements.

Evoke Pharma, Inc.
Notes to Condensed Financial Statements
(Unaudited)

1. Organization and Basis of Presentation

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

Since its inception, the Company has devoted its efforts to developing its sole product, Gimoti™ (metoclopramide) nasal spray, the first and only nasally-administered product indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. On June 19, 2020, the Company received approval from the U.S. Food and Drug Administration (“FDA”) for its 505(b)(2) New Drug Application (“NDA”) for Gimoti. The Company expects to launch commercial sales of Gimoti in the fourth quarter of 2020 through its commercial partner Eversana Life Science Services, LLC. (“Eversana”).

The Company has not yet realized revenues from its planned operations and does not anticipate realizing revenues until it begins commercializing Gimoti. The Company’s activities are subject to the significant risks and uncertainties associated with any specialty pharmaceutical company that is planning to launch its first commercial product, 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 had approximately \$8.0 million in cash and cash equivalents at June 30, 2020, including a \$2 million loan received on June 26, 2020 from a revolving credit facility (the “Eversana Credit Facility”) with Eversana, as discussed in Note 5, the Company anticipates that it will continue to incur losses from operations due to pre-commercialization and commercialization activities, including manufacturing commercial batches of Gimoti, and general and administrative costs to support operations. 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. 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 financial statements do not include any adjustments that may result from the outcome of this uncertainty.

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 2021, excluding any potential additional borrowings from the Eversana Credit Facility and future Gimoti product revenue. This period could be shortened if there are any unanticipated increases in planned spending. Even with the Eversana Credit Facility, the Company may 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 pre-commercialization and commercialization activities. 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 successfully commercialize Gimoti. Because the Company’s business is entirely dependent on the success of Gimoti, if the Company is unable to secure additional financing, successfully commercialize Gimoti or identify and execute on strategic alternatives for Gimoti or the 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.

Impact of COVID-19

To date, the Company has not experienced material disruptions to its financial condition or operations from the novel coronavirus disease (“COVID-19”) pandemic. The Company has continued its pre-commercial activities, including refining the commercial manufacturing process, and with Eversana, has continued preparing for the commercialization of Gimoti. However, there can be no assurance that the Company or Eversana will not be impacted by the COVID-19 pandemic. For example, the COVID-19 pandemic may disrupt the operations of the Company’s third-party suppliers and manufacturers and delay the Company’s manufacturing timelines and commercial launch of Gimoti, and may negatively impact the Company’s ability to successfully commercialize Gimoti and generate product sales. Further, the COVID-19 pandemic and mitigation measures have also had an adverse impact on global economic conditions which could have an adverse effect on the Company’s business and financial condition, including impairing its ability to raise capital when needed. In April 2020, the Company applied for and was approved for a Small Business Administration (“SBA”) loan under the Paycheck Protection Program (“PPP”), established by the Coronavirus Aid, Relief, and Economic Security (“CARES”) Act. On May 1, 2020, the Company received the loan proceeds of approximately \$104,000.

2. Summary of Significant Accounting Policies

The accompanying condensed balance sheet as of December 31, 2019, 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, 2019, which are contained in the Company’s Annual Report on Form 10-K filed with the SEC on March 12, 2020. 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 to FDA. If these CROs and consultants are unable to continue their support, this could adversely affect the operations of the Company.

In addition, the Company relies on third-party suppliers and manufacturer 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 commercial supply demand for Gimoti and the commercialization of Gimoti could be materially and adversely affected.

The Company also relies on Eversana for the management of the pre-commercial launch preparation for Gimoti, distribution services and a dedicated sales team to sell Gimoti. If Eversana is unable to continue managing the launch preparation, serving as a dedicated sales team or distributing Gimoti, the commercialization of Gimoti could be materially and adversely affected.

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, except awards with a performance condition. Awards with performance conditions commence vesting when the satisfaction of the performance condition is probable. The estimation of stock option and ESPP fair value requires management to make estimates and judgments about, among other things, employee exercise behavior, forfeiture rates and volatility of the Company’s common stock. The judgments directly affect the amount of compensation expense that will be recognized.

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

Research and Development Expenses

Research and development costs are expensed as incurred and primarily include compensation and related benefits, stock-based compensation expense and costs paid to third-party contractors for product development activities and drug product materials. The Company has expensed costs relating to the purchase and production of pre-approval inventories as research and development expense in the period incurred prior to FDA approval received June 19, 2020.

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., through its subsidiary Patheon UK Limited, for the 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. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of warrants 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 to do so would be anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Warrants to purchase common stock	2,320,477	2,713,561	2,320,477	2,713,561
Common stock options	4,286,371	3,232,871	4,286,371	3,232,871
Employee stock purchase plan	60,079	—	84,793	—
Total excluded securities	6,666,927	5,946,432	6,691,641	5,946,432

3. Technology Acquisition Agreement

In June 2007, the Company acquired all worldwide rights, data, patents and other related assets associated with Gimoti from Questcor Pharmaceuticals, Inc. ("Questcor") pursuant to an Asset Purchase Agreement. The Company paid Questcor \$650,000 in the form of an upfront payment and \$500,000 in May 2014 as a milestone payment based upon the initiation of the first patient dosing in the Company's Phase 3 clinical trial for Gimoti. In August 2014, Mallinckrodt, plc ("Mallinckrodt") acquired Questcor. As a result of that acquisition, Questcor transferred its rights included in the Asset Purchase Agreement with the Company to Mallinckrodt. In addition to the payments previously made to Questcor, the Company may also be required to make additional milestone payments totaling up to \$52 million. In March 2018, the Company and Mallinckrodt amended the Asset Purchase Agreement to defer development and approval milestone payments, such that, rather than paying two milestone payments based on FDA acceptance for review of the NDA and final product marketing approval, the Company would be required to make a single \$5 million payment on the one-year anniversary after the Company receives FDA approval to market Gimoti. At the time of the Gimoti NDA approval by FDA, the Company recorded the \$5 million payable owed to Mallinckrodt with a due date of June 19, 2021, along with a \$5 million research and development expense.

The remaining \$47 million in milestone payments depend on Gimoti's commercial success. 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, subject to possible extension should any additional, later expiring, patents be granted.

4. 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 six months ended June 30, 2019, the Company sold 6,686,423 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 \$5.7 million, net of commissions and fees. During the six months ended June 30, 2020, the Company sold 1,395,855 shares of common stock at a weighted-average price per share of \$2.42 pursuant to the FBR Sales Agreement and received proceeds of approximately \$3.3 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.

Warrant Exercises

During June 2020, certain holders of warrants converted their warrants to purchase 393,084 shares of the Company's common stock by a "cashless" exercise and received 158,494 shares of the Company's common stock. The warrants had exercise prices ranging from \$2.41 to \$3.12 per share. The shares were issued, and the warrants were originally sold, in reliance upon the registration exemption set forth in Section 4(a)(2) of the Securities Act of 1933.

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.

During the six months ended June 30, 2020, the Company granted stock options to purchase 1,172,000 shares of the Company's common stock. Of such options, 437,500 did not begin vesting until the date that FDA approved the Gimoti NDA. The estimated fair value of each stock option award granted was determined on the date of grant using the Black Scholes option-pricing valuation model with the following weighted-average assumptions for option grants during the three and six months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Common Stock Options				
Risk free interest rate	0.39%	1.80%-2.36%	0.39%-0.96%	1.80%-2.55%
Expected option term	5.5 years	4.27-5.77 years	5.5-6.0 years	4.27-6.0 years
Expected volatility of common stock	103.99%	101.46%-112.58%	99.73%-103.99%	90.34%-112.58%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

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 six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
Employee Stock Purchase Plan		
Risk free interest rate	1.11%	2.52%
Expected term	0.5 years	0.5 years
Expected volatility of common stock	69.72%	130.36%
Expected dividend yield	0.0%	0.0%

The Company recognized non-cash stock-based compensation expense to employees and directors in its research and development and its general and administrative functions during the six months ended June 30, 2020 and 2019 as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	\$ 134,400	\$ 202,117	\$ 254,962	\$ 354,291
General and administrative	228,555	142,724	418,155	369,509
Total stock-based compensation expense	<u>\$ 362,955</u>	<u>\$ 344,841</u>	<u>\$ 673,117</u>	<u>\$ 723,800</u>

As of June 30, 2020, there was approximately \$2.9 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 1.19 years.

5. Commercial Services and Loan Agreements with Eversana

On January 21, 2020, the Company entered into a commercial services agreement (the “Eversana Agreement”) with Eversana for the commercialization of Gimoti. Pursuant to the Eversana Agreement, Eversana will commercialize and distribute Gimoti in the United States. Eversana will manage the marketing of Gimoti to targeted health care providers, as well as the sales and distribution of Gimoti within the United States.

Under the terms of the Eversana Agreement, the Company maintains ownership of the Gimoti NDA, as well as legal, regulatory, and manufacturing responsibilities for Gimoti. Eversana will utilize its internal sales organization, along with other commercial functions, for market access, marketing, distribution and other related patient support services. The Company will record sales for Gimoti and retain more than 80% of net product profits once the parties’ costs are reimbursed. Eversana will receive reimbursement of its commercialization costs pursuant to an agreed upon budget and a percentage of product profits in the mid-to-high teens. Net product profits are the net sales (as defined in the Eversana Agreement) of Gimoti, less (i) reimbursed commercialization costs, (ii) manufacturing and administrative costs set at a fixed percentage of net sales, and (iii) third party royalties. During the term of the Eversana Agreement, Eversana agreed to not market, promote, or sell a competing product in the United States.

The Eversana Agreement terminates on June 19, 2025, unless terminated earlier pursuant to its terms. Upon expiration or termination of the agreement, the Company will retain all profits from product sales and assume all corresponding commercialization responsibilities. Within 30 days after each of the first three annual anniversaries of commercial launch, either party may terminate the agreement if net sales of Gimoti do not meet certain annual thresholds. Either party may terminate the agreement: for the material breach of the other party, subject to a 60-day cure period; in the event an insolvency, petition of the other party is pending for more than 60 days; upon 30 days written notice to the other party if Gimoti is subject to a safety recall; the other party is in breach of certain regulatory compliance representations under the agreement; the Company discontinues the development or production of Gimoti; Gimoti is not commercially launched within nine months of FDA approval; or the net profit is negative for any two consecutive calendar quarters beginning with the first full calendar quarter 24 months following commercial launch; or if there is a change in applicable laws that makes operation of the services as contemplated under the agreement illegal or commercially impractical. Either party may also terminate the Eversana Agreement upon a change of control of the Company’s ownership, subject, in the event that the Company initiates such termination, to a one-time payment equal to between two times and one times annualized service fees paid by the Company under the Eversana Agreement, with such amount based on which year after commercial launch the change of control occurs. Such payment amount would be reduced by the amount of previously reimbursed commercialization costs and profit split paid for the related prior twelve-month period and any revenue which occurred prior to the termination yet to be collected. In addition, Eversana may terminate the Eversana Agreement if the Company withdraws Gimoti from the market for more than 90 days.

In connection with the Eversana Agreement, the Company and Eversana also entered into the Eversana Credit Facility, pursuant to which Eversana agreed to provide a revolving Credit Facility of up to \$5 million to the Company upon FDA approval of the Gimoti NDA, as well as certain other customary conditions. The Eversana Credit Facility terminates on June 19, 2025, unless terminated earlier pursuant to its terms. The Eversana Credit Facility is secured by all of the Company’s personal property other than its intellectual property. Under the terms of the Eversana Credit Facility, the Company cannot grant an interest in its intellectual property to any other person. Each loan under the Eversana Credit Facility will bear interest at an annual rate equal to 10.0%, with such interest due at the end of the loan term. On June 26, 2020, the Company borrowed \$2 million from the Eversana Credit Facility.

The Company may prepay any amounts borrowed under the Eversana Credit Facility at any time without penalty or premium. The maturity date of all amounts, including interest, borrowed under the Eversana Credit Facility will be 90 days after the expiration or earlier termination of the Eversana Agreement. The Eversana Credit Facility also includes events of default, the occurrence and continuation of which provide Eversana with the right to exercise remedies against the Company and the collateral securing the loans under the Eversana Credit Facility, including the Company’s cash. These events of default include, among other things, the Company’s failure to pay any amounts due under the Eversana Credit Facility, an uncured material breach of the representations, warranties and other obligations under the Eversana Credit Facility, the occurrence of insolvency events and the occurrence of a change in control.

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 audited financial statements and accompanying notes thereto for the fiscal year ended December 31, 2019 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 12, 2020. 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, the potential timing of the commercial launch of Gimoti and commercial activities to be conducted by Eversana Life Science Services, LLC, or Eversana, the pricing and reimbursement for Gimoti, future regulatory developments, research and development costs, the timing and likelihood of success, plans and objectives of management for future operations, future results of current and anticipated products and the expected impact of the novel coronavirus, or COVID-19 pandemic, on us or on third parties on whom we rely, 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. This Quarterly Report on Form 10-Q also includes trademarks, tradenames and service marks that are the property of other organizations. 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 and commercialization of drugs to treat gastrointestinal, or GI, disorders and diseases. Since our inception, we have devoted our efforts to developing our sole product, Gimoti (metoclopramide) nasal spray, the first and only nasally-administered product indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. On June 19, 2020, we received approval from the U.S. Food and Drug Administration, or FDA for our 505(b)(2) New Drug Application, or NDA for Gimoti. We expect to launch commercial sales of Gimoti in the fourth quarter of 2020 through our commercial partner Eversana.

Diabetic gastroparesis is a GI disorder affecting millions of patients worldwide, in which the stomach takes too long to empty its contents resulting in serious GI symptoms as well as other system complications. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications. Gimoti is the only nasally-administered drug currently approved in the United States to treat the symptoms in adults with acute and recurrent diabetic gastroparesis.

On January 21, 2020, we entered into an agreement with Eversana for the commercialization of Gimoti, or the Eversana Agreement. Pursuant to the Eversana Agreement, Eversana will commercialize and distribute Gimoti in the United States. Eversana will manage the marketing of Gimoti to targeted health care providers, as well as the sales and distribution of Gimoti within the United States.

Eversana also provided a \$5 million revolving credit facility, or Eversana Credit Facility, which became available upon FDA approval of Gimoti. On June 26, 2020, we borrowed \$2 million under the Eversana Credit Facility.

We have not generated any revenue from Gimoti 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. These 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 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 June 30, 2020, we had cash and cash equivalents of approximately \$8.0 million. Current cash on hand is intended to fund commercialization activities for Gimoti, including manufacturing commercial batches 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 2021, excluding any potential additional borrowings from the Eversana Credit Facility and future Gimoti product revenue. This period could be shortened if there are any unanticipated increases in planned spending, including as a result of the COVID-19 pandemic. Even with the Eversana Credit Facility, we may be required to raise additional funds in order to continue as a going concern. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing, successfully commercialize Gimoti or identify and execute other 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.

Impact of COVID-19

To date, we have not experienced material disruptions to our financial condition or operations from the novel coronavirus disease, or COVID-19 pandemic. We have continued our commercial preparation activities, including the commercial manufacturing process, and with Eversana, have continued preparing for the commercialization of Gimoti. However, there can be no assurance that we or Eversana will not be impacted by the COVID-19 pandemic. For example, the COVID-19 pandemic may disrupt the operations of our third-party suppliers and manufacturers and delay our manufacturing timelines and commercial launch of Gimoti and may negatively impact our ability to successfully commercialize Gimoti and generate product sales. Further, the COVID-19 pandemic and mitigation measures have also had an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. In April 2020, we applied for and were approved for a Small Business Administration, or SBA, loan under the Paycheck Protection Program, or PPP, established by the Coronavirus Aid, Relief, And Economic Security, or CARES Act. On May 1, 2020, we received loan proceeds of approximately \$104,000. Based on the SBA guidelines, we believe that the balance of the loan and accrued interest will be forgiven in accordance with the terms of the PPP loan.

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 FDA approval to market Gimoti. At the time of the Gimoti NDA approval by FDA, we recorded the \$5 million payable owed to Mallinckrodt with a due date of June 19, 2021, along with a \$5 million research and development expense.

The remaining \$47 million in milestone payments depend on Gimoti's commercial success. 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, subject to possible extension should any additional, later expiring, patents be granted.

Financial Operations Overview

Revenue

To date, we have not generated any revenue. Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Gimoti, which we expect to launch in the fourth quarter of 2020 through our commercial partner Eversana. If we or Eversana fail to successfully launch Gimoti, we may never generate revenues and our results of operations and financial position will be adversely affected.

Research and Development Expenses

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

- clinical and regulatory-related costs;
- expenses incurred under agreements with contract research organizations, or CROs;
- pre-commercial 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. With the FDA approval of Gimoti, we expect research and development costs to decrease and shift to commercialization and selling costs. However, we expect to begin planning for an FDA post-marketing commitment pharmacokinetics trial of Gimoti. This commitment will likely begin in 2021 and will characterize dose proportionality of a lower dosage strength of Gimoti to accommodate patients that may require further dosage adjustments. We are unable to estimate with any certainty the costs we will incur related to such future trial, or the regulatory review of such lower dosage of Gimoti, though such costs may be significant. Clinical development timelines, the probability of success and development costs can differ materially from expectations.

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

- per subject trial costs;
- the number of sites included in the trials;
- 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; and
- the duration of subject follow-up.

General and Administrative Expenses

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

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 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, 2019, which was filed with the SEC on March 12, 2020.

Other Information

None.

Results of Operations

Comparison of Three Months Ended June 30, 2020 and 2019

The following table summarizes the results of our operations for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		Increase/ (Decrease)
	2020	2019	
Research and development expenses	\$ 5,782,094	\$ 1,205,599	\$ 4,576,495
General and administrative expenses	\$ 1,182,872	\$ 918,139	\$ 264,733

Research and Development Expenses. Research and development expenses for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 increased by approximately \$4.6 million. The increase during the three months ended June 30, 2020 is primarily due to recording a \$5 million expense in June 2020 upon achieving a technology acquisition milestone related to FDA's approval of Gimoti. Although the expense was recorded when incurred, the payment is not due to Mallinckrodt until June 19, 2021. During the three months ended June 30, 2020, we also incurred expenses responding to requests for additional information from FDA related to the NDA and preparing for future manufacturing and the commercial launch of Gimoti. In addition to the milestone expense, we incurred other costs during the three months ended June 30, 2020 including approximately \$378,000 for wages, taxes and employee insurance, including approximately \$134,000 of stock-based compensation expense, and approximately \$347,000 related to manufacturing. With FDA approval of Gimoti, we expect research and development expenses to decrease as we shift our focus more to commercialization and selling activities. However, we expect to begin planning for a post-marketing commitment pharmacokinetics trial of Gimoti, which is likely to begin in 2021.

In 2019, we incurred expenses primarily related to responding to requests for additional information from FDA and manufacturing registration batches of Gimoti as required by FDA. Costs incurred in 2019 included approximately \$758,000 for wages, taxes and employee insurance, including approximately \$202,000 of stock-based compensation expense, and approximately \$436,000 related to manufacturing.

General and Administrative Expenses. General and administrative expenses for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 increased by approximately \$265,000. Costs incurred in 2020 primarily included approximately \$610,000 for wages, taxes and employee insurance, including approximately \$229,000 of stock-based compensation expense, and approximately \$476,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company. Of the general and administrative expenses incurred during the three months ended June 30, 2020, approximately \$312,000 related to pre-commercialization activities. Costs incurred in 2019 primarily included approximately \$363,000 for wages, taxes and employee insurance, including approximately \$143,000 of stock-based compensation expense, approximately \$343,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company, approximately \$112,000 for outside consultants, and approximately \$30,000 for pre-commercialization costs. General and administration costs are expected to increase in future periods as we continue to progress with the commercialization of Gimoti.

Comparison of Six Months Ended June 30, 2020 and 2019

The following table summarizes the results of our operations for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,		Increase/ (Decrease)
	2020	2019	
Research and development expenses	\$ 6,245,946	\$ 1,952,481	\$ 4,293,465
General and administrative expenses	\$ 2,512,707	\$ 2,141,152	\$ 371,555

Research and Development Expenses. Research and development expenses for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 increased by approximately \$4.3 million. The increase during the six months ended June 30, 2020 is primarily due to recording a \$5 million expense in June 2020 upon achieving a technology acquisition milestone related to FDA's approval of Gimoti. Although the expense was recorded when incurred, the payment is not due to Mallinckrodt until June 19, 2021. During the six months ended June 30, 2020, we also incurred expenses responding to requests for additional information from FDA related to the NDA and preparing for future manufacturing and the commercial launch of Gimoti. Costs incurred in 2020 included approximately \$749,000 for wages, taxes and employee insurance, including approximately \$255,000 of stock-based compensation expense, and approximately \$423,000 related to manufacturing.

In 2019, we incurred expenses primarily related to responding to requests for additional information from FDA and manufacturing registration batches of Gimoti as required by FDA. Costs incurred in 2019 included approximately \$1.3 million for wages, taxes and employee insurance, including approximately \$354,000 of stock-based compensation expense, approximately \$539,000 related to

manufacturing, and approximately \$75,000 related to responding to FDA questions on the NDA and the Complete Response Letter from FDA for the NDA.

General and Administrative Expenses. General and administrative expenses for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 increased by approximately \$372,000. Costs incurred in 2020 primarily included approximately \$1.2 million for wages, taxes and employee insurance, including approximately \$418,000 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. Of the general and administrative expenses incurred during the six months ended June 30, 2020, approximately \$412,000 related to pre-commercialization activities. Costs incurred in 2019 primarily included approximately \$980,000 for wages, taxes and employee insurance, including approximately \$370,000 of stock-based compensation expense, approximately \$834,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company, approximately \$114,000 for outside consultants and approximately \$66,000 for pre-commercialization costs.

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 six months ended June 30, 2019, we sold 6,686,423 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 \$5.7 million, net of commissions and fees. During the six months ended June 30, 2020, we sold 1,395,855 shares of common stock at a weighted-average price per share of \$2.42 pursuant to the FBR Sales Agreement and received proceeds of approximately \$3.3 million, net of commissions and fees.

As of July 31, 2020, we had the capacity to issue up to approximately \$1.7 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.

Under current SEC regulations, if at the time we file our Annual Report on 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. During June 2020, our public float exceeded \$75 million, thereby allowing us to conduct primary offerings without being constrained by the baby shelf rules. We will remain unconstrained by the baby shelf rules under our Form S-3 shelf registration statement until the date we file a new registration statement or our Form 10-K for the fiscal year ending December 31, 2020, at which time if our public float is less than \$75 million, the amount of securities we may sell under a Form S-3 registration statement will again be limited by the baby shelf rules.

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 connection with the Eversana Agreement, we entered into the Eversana Credit Facility, pursuant to which Eversana agreed to provide a revolving Credit Facility of up to \$5 million to us upon FDA approval of the Gimoti NDA, as well as certain other customary conditions. The Eversana Credit Facility terminates on June 19, 2025, unless terminated earlier pursuant to its terms. The Eversana Credit Facility is secured by all of the Company's personal property other than its intellectual property. Under the terms of the Eversana Credit Facility, we cannot grant an interest in our intellectual property to any other person. Each loan under the Eversana Credit Facility will bear interest at an annual rate equal to 10.0%, with such interest due at the end of the loan term. On June 26, 2020, we borrowed \$2 million from the Eversana Credit Facility.

Management concluded that there is substantial doubt about 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 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 2021, excluding any potential additional borrowings from the Eversana Credit Facility and future Gimoti product revenue. This period could be shortened if there are unanticipated increases in planned spending, including as a result of the COVID-19 pandemic. Even with the Eversana Credit Facility, we may 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. Because our business is

entirely dependent on the success of Gimoti, if we are unable to secure additional financing, successfully commercialize Gimoti, or identify and execute other 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 pre-commercialization and commercialization activities, including 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.

We expect to continue to incur expenses as we:

- continue the commercialization activities for Gimoti;
- manufacture the commercial batches of Gimoti;
- conduct additional development activities as we seek additional indications;
- 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 six months ended June 30, 2020 and 2019:

	Six Months Ended		Increase/ (Decrease)
	June 30,		
	2020	2019	
Net cash used in operating activities	\$ (3,107,975)	\$ (3,555,313)	\$ (447,338)
Net cash provided by financing activities	\$ 5,434,534	\$ 5,676,388	\$ (241,854)
Net increase in cash and cash equivalents	\$ 2,326,559	\$ 2,121,075	\$ 205,484

Operating Activities. The primary use of our cash has been to fund our clinical research, prepare our NDA, manufacture Gimoti, and other general operations. The cash used in operating activities during the six months ended June 30, 2020 was primarily related to ongoing communication with FDA related to the resubmitted NDA, and pre-approval and pre-commercialization activities. The cash used in operating activities during the six months ended June 30, 2019 was primarily related to ongoing communication with FDA related to the NDA and pre-approval and pre-commercialization activities. We expect that cash used in operating activities will increase in 2020 due to pre-commercialization and commercialization activities, including manufacturing of Gimoti.

Financing Activities. During the six months ended June 30, 2019, we received net proceeds of approximately \$5.7 million from the sale of 6,686,423 shares of common stock pursuant to the FBR Sales Agreement. During the six months ended June 30, 2020, we received net proceeds of approximately \$3.3 million from the sale of 1,395,855 shares of common stock pursuant to the FBR Sales Agreement, \$2 million from borrowings under the Eversana Credit Facility, approximately \$104,000 from the PPP loan, and \$21,250 from the sale of 25,000 shares of common stock pursuant to our Employee Stock Purchase Plan.

The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- the costs of commercialization activities, including costs associated with commercial manufacturing;
- the commercial success of Gimoti, including competition with well-established products already approved by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- the impact of the COVID-19 pandemic on us or on third parties on whom we rely;
- our ability to manufacture sufficient quantities of Gimoti to meet demand, including whether our contract manufacturers, suppliers, and/or consultants are able to meet appropriate timelines;
- our ability to access the Eversana Credit Facility, which remains subject to certain customary conditions;
- the progress and costs of the post-marketing commitment to conduct a pharmacokinetics trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti and the costs of any additional clinical trials we may pursue to expand the indication of Gimoti;
- our ability to obtain, maintain and enforce our patents and other intellectual property rights, and the costs incurred to do so;

- 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.

Off-Balance Sheet Arrangements

Through June 30, 2020, 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 six months ended June 30, 2020 to the information regarding our contractual obligations that was disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 12, 2020, except for the \$2 million borrowing from Eversana as discussed in Note 5 in our Notes to Condensed Financial Statements. In addition, with the approval of the Gimoti NDA, we are now committed to pay Mallinckrodt \$5 million as discussed in Note 3 in our Notes to Condensed Financial Statements.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

As of June 30, 2020, 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, 2019, filed with the SEC on March 12, 2020.

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), as of June 30, 2020 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 June 30, 2020.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended June 30, 2020 that materially affect, 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, 2019, filed with the SEC on March 12, 2020, other than as set forth below:

Risks Related to our Business, including the Regulatory Compliance and Commercialization of our Product, Gimoti

Our business is entirely dependent on the success of Gimoti, which has not launched commercially and may never generate sales or become profitable.

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.

Because our business is entirely dependent on the success of Gimoti, if we are unable to successfully commercialize this product, 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 commercial success of Gimoti is subject to a number of additional risks, including the following:

- Gimoti will compete with well-established products, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- our reliance on Eversana to commercialize Gimoti;
- our ability, with Eversana, to hire and train a sales team for Gimoti;
- the impact of the COVID-19 pandemic on our ability to generate sales for Gimoti;
- we may not be able to develop market demand for, and later increase sales of, Gimoti through our sales and marketing efforts;
- our ability to obtain adequate levels of coverage and reimbursement for Gimoti from commercial health plans and government health programs;
- 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;
- our ability to successfully conduct a post-marketing approval pharmacokinetics trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti, including the risk that FDA may disagree with the design of the clinical trial;
- patients taking Gimoti may suffer adverse effects for reasons that may or may not be related to Gimoti, which may adversely affect Gimoti’s commercial profile; and
- we may not be able to obtain, maintain and enforce our patents and other intellectual property rights.

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 2021, excluding the \$3.0 million remaining amount available under the Eversana Credit Facility and future Gimoti product revenue. This period could be shortened if there are any significant increases in planned spending other than anticipated. Even with the remaining amount available under the Eversana Credit Facility or any product revenue, we will likely 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 we will be able to raise additional funds on acceptable terms, or at all. Because our business is entirely dependent on the success of Gimoti, if we are unable to secure additional financing, successfully commercialize Gimoti or identify and execute on other commercialization 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 costs of commercialization activities, including costs associated with commercial manufacturing;
- the commercial success of Gimoti, including competition with well-established products already approved by FDA, including oral and intravenous forms of metoclopramide, the same active ingredient in the nasal spray for Gimoti;
- the impact of the COVID-19 pandemic on us or on third parties on whom we rely
- our ability to manufacture sufficient quantities of Gimoti to meet demand, including whether our contract manufacturers, suppliers, and/or consultants are able to meet appropriate timelines;
- the progress and costs of the post-marketing commitment pharmacokinetics trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti and the costs of any additional clinical trials we may pursue to expand the indication of Gimoti;
- our ability to obtain, maintain and enforce our patents and other intellectual property rights and the costs incurred in doing so;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; and
- costs associated with any other product candidates that we may develop, in-license or acquire.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. Furthermore, the issuance of additional shares or other securities by us, or the possibility of such issuance, may cause the market price of our shares to decline and dilute the holdings of our existing stockholders. If we raise additional funds by incurring debt, the terms of the debt may involve significant cash payment obligations, as well as covenants and specific financial ratios that may restrict our ability to operate our business. We cannot provide any assurance that our existing capital resources will be sufficient to enable us to identify or execute a viable plan for continued clinical development of Gimoti or to otherwise survive as a going concern.

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

In connection with FDA's approval of Gimoti, we committed to conduct a pharmacokinetic trial to characterize the dose proportionality of a lower dose strength compared to the current 15 mg dose strength. We expect to initiate this trial in 2021. We do not know whether any trials will produce data on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- FDA placing a clinical trial on hold;
- subjects experiencing severe or unexpected drug-related adverse effects;
- a facility manufacturing Gimoti, or any of its components, being ordered by FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of FDA's current Good Manufacturing Practices, or cGMP, or other applicable requirements, or infections or cross-contaminations of a product candidate in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practice and regulatory requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical trial sites by FDA or the finding of regulatory violations by FDA or an institutional review board, or IRB, that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire trial, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications; or

- an IRB refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Product development costs will increase if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of or if we, FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical trial sites suspend or terminate any of our clinical trials, the commercial prospects for our product candidate may be harmed and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

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

Use of Gimoti or any future product candidates we may develop could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of the approved labeling, or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

If we or others identify undesirable side effects, or other previously unknown problems, with Gimoti, a number of potentially significant negative consequences could result, including:

- regulatory authorities may add new limitations for distribution and marketing of the product;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- FDA could suspend or withdraw approval of the product, or refuse to approve pending NDA supplements;
- FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Moreover, if any future product candidates we may develop are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial prospects for the product candidate, if approved. Undesirable side effects could cause us or regulatory authorities to interrupt, delay or halt clinical trials, result in a more restrictive label than proposed, or delay or cause the denial of regulatory approvals by FDA or comparable foreign regulatory authorities. The drug-related side effects could also affect patient recruitment for our clinical trials, or the ability of enrolled patients to complete the trials, or result in potential product liability claims. We may also be required to modify our plans for future studies based on findings in our ongoing clinical trials. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations. Any of these occurrences may harm our business, financial condition and prospects significantly.

Undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of Gimoti, or our future product candidates, if approved, and could substantially increase the costs of commercializing and developing such products or product candidates.

Our business may be impacted by epidemic diseases such as the recent global outbreak of the COVID-19 coronavirus.

The recent outbreak of COVID-19, which has been declared by the World Health Organization to be a pandemic, has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, or our third-party suppliers and manufacturers may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. The continued spread of COVID-19 and the measures taken by the governments of countries affected could disrupt the supply chain and the manufacture or shipment of drug substance, sprayer and finished drug product for Gimoti for commercial sale, cause us to delay or materially modify our commercial launch plans and hiring strategy, which could increase costs or decrease potential revenues following any commercial launch and have a material adverse effect on our business,

financial condition and results of operations. Moreover, to the extent any of these risks and uncertainties adversely impact us in the ways described above or otherwise, they may also have the effect of heightening many of the other risks set forth in our Annual Report on Form 10-K for the year ended December 31, 2019. The COVID-19 pandemic and mitigation measures have also had an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 pandemic impacts our regulatory review timelines, manufacturing capabilities and commercial launch plans and other results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

Disruptions at FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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
4.9 (9)	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
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.
- (9) Incorporated by reference to the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2020.

* 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: August 6, 2020

By: /s/ David A. Gonyer

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

Date: August 6, 2020

By: /s/ Matthew J. D'Onofrio

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

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: August 6, 2020

/s/ David A. Gonyer

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

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: August 6, 2020

/s/ Matthew J. D'Onofrio

Matthew J. D'Onofrio

Executive Vice President, Chief Business Officer,

Treasurer and Secretary

(Principal Financial Officer)

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 June 30, 2020 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: August 6, 2020

/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.

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 June 30, 2020, 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: August 6, 2020

/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.