

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES 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

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

As of November 4, 2022, the registrant had 3,343,070 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 September 30, 2022 (Unaudited) and December 31, 2021</u>	1
<u>Condensed Statements of Operations for the three and nine months ended September 30, 2022 and 2021 (Unaudited)</u>	2
<u>Condensed Statements of Stockholders' Equity for the three and nine months ended September 30, 2022 and 2021 (Unaudited)</u>	3
<u>Condensed Statements of Cash Flows for the nine months ended September 30, 2022 and 2021 (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>	13
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	21
<u>Item 4. Controls and Procedures</u>	21
<u>PART II. OTHER INFORMATION</u>	21
<u>Item 1. Legal Proceedings</u>	21
<u>Item 1A. Risk Factors</u>	22
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
<u>Item 3. Defaults Upon Senior Securities</u>	23
<u>Item 4. Mine Safety Disclosures</u>	23
<u>Item 5. Other Information</u>	23
<u>Item 6. Exhibits</u>	24
<u>SIGNATURES</u>	25

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

	September 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 12,350,024	\$ 9,144,710
Accounts receivable, net	674,970	295,193
Prepaid expenses	—	923,746
Inventory	220,304	185,534
Other current assets	11,551	11,551
Total current assets	13,256,849	10,560,734
Operating lease right-of-use asset	153,671	12,428
Total assets	<u>\$ 13,410,520</u>	<u>\$ 10,573,162</u>
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,020,690	\$ 874,028
Accrued compensation	716,993	519,317
Operating lease liability	140,300	12,428
Total current liabilities	1,877,983	1,405,773
Long-term liabilities		
Operating lease liability, non-current	13,371	—
Note payable	5,000,000	5,000,000
Accrued interest payable	986,268	612,295
Total long-term liabilities	5,999,639	5,612,295
Total liabilities	<u>7,877,622</u>	<u>7,018,068</u>
Stockholders' equity:		
Common stock, \$0.0001 par value; authorized shares - 50,000,000; issued and outstanding shares - 3,343,070 and 2,721,373 at September 30, 2022 and December 31, 2021, respectively	334	272
Additional paid-in capital	119,376,486	110,977,835
Accumulated deficit	(113,843,922)	(107,423,013)
Total stockholders' equity	5,532,898	3,555,094
Total liabilities and stockholders' equity	<u>\$ 13,410,520</u>	<u>\$ 10,573,162</u>

See accompanying notes to these unaudited condensed financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net product sales	\$ 832,100	\$ 930,449	\$ 1,712,275	\$ 1,257,505
Operating expenses:				
Cost of goods sold	89,775	58,435	180,310	191,439
Research and development	40,388	81,699	273,582	554,753
Selling, general and administrative	2,614,488	2,635,161	7,334,738	7,115,605
Total operating expenses	<u>2,744,651</u>	<u>2,775,295</u>	<u>7,788,630</u>	<u>7,861,797</u>
Loss from operations	(1,912,551)	(1,844,846)	(6,076,355)	(6,604,292)
Other income (expense):				
Forgiveness of paycheck protection loan and accrued interest	—	—	—	105,130
Interest income	24,714	1,421	29,419	7,596
Interest expense	<u>(126,027)</u>	<u>(126,027)</u>	<u>(373,973)</u>	<u>(374,024)</u>
Total other income (expense)	<u>(101,313)</u>	<u>(124,606)</u>	<u>(344,554)</u>	<u>(261,298)</u>
Net loss	<u>\$ (2,013,864)</u>	<u>\$ (1,969,452)</u>	<u>\$ (6,420,909)</u>	<u>\$ (6,865,590)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.60)</u>	<u>\$ (0.73)</u>	<u>\$ (2.09)</u>	<u>\$ (2.57)</u>
Weighted-average shares used to compute basic and diluted net loss per share	<u>3,343,070</u>	<u>2,711,871</u>	<u>3,077,145</u>	<u>2,669,070</u>

See accompanying notes to these unaudited condensed financial statements.

Evoked Pharma, Inc.

Condensed Statements of Stockholders' Equity

(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2022	2,721,373	\$ 272	\$ 110,977,835	\$ (107,423,013)	\$ 3,555,094
Stock-based compensation expense	—	—	381,061	—	381,061
Issuance of common stock, net of costs of \$3,548	21,783	2	171,519	—	171,521
Net loss	—	—	—	(2,173,665)	(2,173,665)
Balance at March 31, 2022	2,743,156	274	111,530,415	(109,596,678)	1,934,011
Stock-based compensation expense	—	—	366,924	—	366,924
Issuance of common stock net of costs of \$145,445	599,914	60	7,123,395	—	7,123,455
Net loss	—	—	—	(2,233,380)	(2,233,380)
Balance at June 30, 2022	3,343,070	334	119,020,734	(111,830,058)	7,191,010
Stock-based compensation expense	—	—	355,752	—	355,752
Net loss	—	—	—	(2,013,864)	(2,013,864)
Balance at September 30, 2022	3,343,070	\$ 334	\$ 119,376,486	\$ (113,843,922)	\$ 5,532,898

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2021	2,218,496	\$ 222	\$ 95,670,216	\$ (98,885,061)	\$ (3,214,623)
Stock-based compensation expense	—	—	561,348	—	561,348
Issuance of common stock, net of costs of \$1,304,846	479,166	48	13,070,106	—	13,070,154
Net loss	—	—	—	(2,605,495)	(2,605,495)
Balance at March 31, 2021	2,697,662	270	109,301,670	(101,490,556)	7,811,384
Stock-based compensation expense	—	—	399,411	—	399,411
Issuance of common stock from stock option exercises	5,618	1	45,453	—	45,454
Net loss	—	—	—	(2,290,643)	(2,290,643)
Balance at June 30, 2021	2,703,280	271	109,746,534.00	(103,781,199)	5,965,606
Stock-based compensation expense	—	—	463,995	—	463,995
Issuance of common stock, net of costs of \$6,421	18,091	2	313,105	—	313,107
Net loss	—	—	—	(1,969,452)	(1,969,452)
Balance at September 30, 2021	2,721,371	\$ 273	\$ 110,523,634	\$ (105,750,651)	\$ 4,773,256

See accompanying notes to these unaudited condensed financial statements.

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

	Nine Months Ended September 30,	
	2022	2021
Operating activities		
Net loss	\$ (6,420,909)	\$ (6,865,590)
Adjustments to reconcile net loss to net cash used in operating activities:		
Forgiveness of paycheck protection loan and accrued interest	—	(105,130)
Stock-based compensation expense	1,103,737	1,424,754
Non-cash lease expense	12,428	—
Change in operating assets and liabilities:		
Accounts receivable, net	(379,777)	(198,855)
Prepaid expenses, inventory and other assets	888,976	1,055,913
Accounts payable and other current liabilities	146,662	(835,632)
Accrued compensation	197,676	(205,442)
Accrued interest expense	373,973	374,236
Operating lease liabilities	(12,428)	—
Milestone payable	—	(5,000,000)
Net cash used in operating activities	(4,089,662)	(10,355,746)
Financing activities		
Proceeds from issuance of common stock	—	14,375,000
Payment of common stock offering costs	—	(1,304,846)
Proceeds from issuance of common stock from ATM	7,443,969	319,528
Payment of common stock offering costs from ATM	(148,993)	(6,421)
Proceeds from issuance of common stock from exercise of stock options	—	45,454
Net cash provided by financing activities	7,294,976	13,428,715
Net increase in cash and cash equivalents	3,205,314	3,072,969
Cash and cash equivalents at beginning of period	9,144,710	8,068,939
Cash and cash equivalents at end of period	\$ 12,350,024	\$ 11,141,908
Supplemental disclosure of non-cash investing and financing activities		
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	\$ 153,671	\$ —
Forgiveness of paycheck protection loan and accrued interest	\$ —	\$ 105,130

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 under the laws of 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 launched U.S. commercial sales of Gimoti in October 2020 through its commercial partner Eversana Life Science Services, LLC (“Eversana”).

The Company’s activities are subject to the significant risks and uncertainties associated with any specialty pharmaceutical company that has launched its first commercial product, including market acceptance of the product and the potential need to obtain additional funding for its operations.

Going Concern

The financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. 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. As of September 30, 2022, the Company had approximately \$12.4 million in cash and cash equivalents. The Company anticipates that it will continue to incur losses from operations due to commercialization activities, including manufacturing Gimoti, conducting the post-marketing commitment single-dose pharmacokinetics (“PK”) clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti, and for other general and administrative costs to support the Company’s operations. As a result, the Company believes that there is substantial doubt about its ability to continue as a going concern for one year after the date these financial statements are issued. The 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 anticipates that it will be required to raise additional funds through debt, equity or other forms of financing, such as potential collaboration arrangements, to fund future operations and continue as a going concern.

There can be no assurance that additional financing will be available when needed or on acceptable terms. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, and/or suspend or curtail 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, 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

The Company began its commercial sales of Gimoti with Eversana in October 2020. Due to the COVID-19 pandemic, the Company experienced disruptions to its sales activities, including its efforts to reach physicians and customers. For example, Eversana’s commercialization efforts at the time the Company launched Gimoti were adversely affected by operational restrictions imposed on its sales force from quarantines, travel restrictions and bans, and other governmental restrictions related to COVID-19. As a result of these restrictions, Eversana’s sales force was restricted from conducting in-person interactions with certain physicians and customers and was restricted to conducting Gimoti educational and promotional activities virtually in certain circumstances, which impacted Eversana’s ability to more actively market Gimoti. Starting in the fourth quarter of 2021, certain physician offices began to allow more frequent in-person interactions, which has helped to increase the educational and promotional activities of the sales force. The Company anticipates that it and Eversana will continue to be impacted by the COVID-19 pandemic to some extent.

The COVID-19 pandemic has not significantly disrupted the operations of the Company's third-party suppliers and manufacturers or delayed the Company's manufacturing timelines of Gimoti, but may negatively impact the Company's ability to successfully commercialize Gimoti and generate product sales in the future. Further, the COVID-19 pandemic and related mitigation measures have also had an adverse impact on global economic conditions which could have an adverse effect on the Company's future business and financial condition, including impairing its ability to raise capital when needed.

In March 2020, the Coronavirus Aid, Relief, and Economic Security ("CARES") Act was enacted in response to the COVID-19 pandemic. In April 2020, the Company applied for and was approved for a Small Business Administration ("SBA") loan under the Paycheck Protection Program, established by the CARES Act. On May 1, 2020, the Company received the loan proceeds of approximately \$104,000. In January 2021, the Company received notice that its loan and accrued interest were forgiven by the SBA.

Notice of Delisting and Reverse Stock Split

On December 29, 2021, the Company received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq Capital Market.

In accordance with Nasdaq listing rules, the Company was provided an initial period of 180 calendar days, or until June 27, 2022, to regain compliance. The letter stated that Nasdaq will provide written notification that the Company has achieved compliance with its rules if at any time before June 27, 2022 the bid price of the Company's common stock closes at \$1.00 per share or more for a minimum of ten consecutive business days. The Nasdaq letter had no immediate effect on the listing or trading of the Company's common stock and the common stock continued to trade on The Nasdaq Capital Market.

On April 27, 2022, the Company's stockholders granted the board of directors the authority to effect a reverse stock split of the Company's outstanding common stock. On May 23, 2022 the Company effected a 1-for-12 reverse stock split of the shares of the Company's common stock (the "Reverse Stock Split"). The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. All of the Company's issued and outstanding common stock, warrants to purchase common stock, and options to purchase common stock have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

On June 7, 2022, the Company received notice from Nasdaq stating that the closing price of the Company's common stock had been at \$1.00 per share or greater for the prior ten consecutive business days and that the Company had regained compliance with the minimum \$1.00 per share requirement.

2. Summary of Significant Accounting Policies

The accompanying condensed balance sheet as of December 31, 2021, 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 statement 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, 2021, which are contained in the Company's Annual Report on Form 10-K filed with the SEC on March 8, 2022. 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 revenues and 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 activities. If the CROs and consultants are unable to continue their support, this could adversely affect the Company's operations.

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

The Company also relies on a dedicated third-party sales team to sell Gimoti. If such third-party organization is unable to continue serving as a dedicated sales team, the commercialization of Gimoti could be materially and adversely affected.

Accounts Receivable

Accounts receivable are recorded net of allowance for doubtful accounts. Estimates for allowances for doubtful accounts are determined based on existing contractual obligations and historical payment patterns. The allowance for doubtful accounts was zero at September 30, 2022 and December 31, 2021 and no bad debt expense was recorded for the three and nine months ended September 30, 2022 and 2021.

Inventory

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 depends on third-party contract manufacturers for all of its required raw materials, drug substance and finished product for its commercial manufacturing. 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 the manufacturing contractors.

Subsequent to FDA approval, the Company began manufacturing Gimoti for commercialization and began capitalizing inventory at that time. The Company's inventory consisted of approximately \$150,000 of raw materials at September 30, 2022 and December 31, 2021, and approximately \$71,000 and \$35,000 of finished goods inventory at September 30, 2022 and December 31, 2021, respectively. Inventories are stated at the lower of cost (first-in first-out basis) or net realizable value. Inventory at December 31, 2021 was written down by \$30,000 due to establishing a reserve for obsolescence, and this inventory was subsequently destroyed. The new cost basis and its value is not to be subsequently increased based upon changes in underlying facts and circumstances. The Company's raw materials inventory is held at its third-party suppliers and its work-in-process and finished goods inventory is held at its manufacturer and at Eversana. The Company records such inventory as consigned inventory.

Revenue Recognition

The Company's ability to generate revenue and become profitable depends on its ability to successfully commercialize Gimoti, which was launched in the United States through prescription in October 2020 through the Company's commercial partner Eversana. If the Company or Eversana fail to successfully grow and maintain sales of Gimoti, the Company may never generate significant revenues and its results of operations and financial position will be adversely affected.

In accordance with Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*, the Company recognizes revenue when a customer obtains control of promised goods in an amount that reflects the consideration the Company expects to receive in exchange for the goods provided. Customer control is determined upon the customer's physical receipt of the product. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: identify the contracts with the customer; identify the performance obligations in the contract; determine the transaction price; allocate the transaction price to the performance obligations in the contract; and recognize revenue when (or as) it satisfies a performance obligation. At contract inception, the Company assesses the goods promised within each contract and determines those that are performance obligations and assesses whether each promised good is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when the customer obtains control of the product.

Product sales are recorded at the transaction price, which may include variable considerations for co-payment assistance to commercially insured patients meeting certain eligibility requirements, as well as to uninsured patients. Co-payment assistance is recorded as an offset to gross revenue at the time revenue from the product sale is recognized based on expected and actual program participation. Co-pay liabilities are estimated using prescribing data available from customers. Actual amounts of consideration ultimately received may materially differ from the Company's estimates. If actual results in the future vary from estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. Liabilities for co-pay assistance of approximately \$54,000 and \$44,000 at September 30, 2022 and December 31, 2021, respectively, are classified as accounts payable and accrued expenses in the balance sheets.

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 a performance condition 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. The Company accounts for forfeitures as the forfeitures occur.

Research and Development Expenses

Research and development costs are expensed as incurred and primarily include compensation and related benefits, stock-based compensation expense, costs paid to third-party contractors for product development activities and drug product materials, and technology acquisition milestones. The Company will expense the clinical, regulatory and manufacturing costs related to the post-marketing commitment to conduct a single dose PK clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti, as well as other costs that may occur for any additional clinical trials the Company may pursue to expand the indication of Gimoti.

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 stock and common stock equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of warrants to purchase common stock, and options to purchase common stock under the Company's equity incentive plan.

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 for the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Warrants to purchase common stock	—	139,972	—	139,972
Common stock options	491,851	429,194	491,851	429,194
Total excluded securities	491,851	569,166	491,851	569,166

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, ("FASB") issued ASU 2016-13, *Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. This update is effective for annual periods beginning after December 15, 2022, and interim periods within those periods, and early adoption is permitted. The Company expects to adopt the standard on its effective date in the first quarter of 2023. The Company also believes the adoption will modify the way we analyze financial instruments, but currently do not expect the adoption to have a material financial impact on our financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options*, or Subtopic 470-20 and *Derivatives and Hedging—Contracts in Entity's Own Equity*, or Subtopic 815-40: *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. Specifically, ASU 2020-06 simplifies accounting for the issuance of convertible instruments by removing major separation models required under current GAAP. In addition, the ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and simplifies the diluted earnings per share, or EPS, calculation in certain areas. ASU 2020-06 will be effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. The Company's early adoption of this accounting standard on January 1, 2022 did not have a material impact on the Company's financial statements and related disclosures.

3. Commitments and Contingencies

Leases

The Company's operating lease for office space in Solana Beach, California was extended in February 2022 and had an expiration date of October 31, 2022, subject to the landlord's option to cancel upon 30 days written notice. The Company extended this lease for an additional 12 months, effective November 1, 2022.

As of September 30, 2022, the Company has future minimum lease payments under its existing facility lease of approximately \$39,000 payable in 2022 and \$134,000 payable in 2023. The remaining lease term is 1.08 years and the discount rate used was 10% for the office lease as of September 30, 2022.

The short-term lease expense of \$37,281 and \$111,843 is included in the general and administrative expense for the three and nine months ended September 30, 2022, respectively. The operating lease expense of \$35,816 and \$92,588 was included in general and administrative expense for the three and nine months ended on September 30, 2021, respectively. The cash paid for the operating lease liability was \$37,281 and \$99,417 for the three and nine months ended on September 30, 2021, respectively. The cash paid for the operating lease liability was \$12,427 for the three and nine months ended on September 30, 2022.

Legal Proceedings

On February 25, 2022, the Company received a letter notifying us that Teva Pharmaceuticals, Inc. ("Teva") submitted to FDA an abbreviated new drug application, or ANDA, for a generic version of Gimoti (metoclopramide hydrochloride) nasal spray eq. 15 mg base/spray that contains Paragraph IV certifications with respect to two of our patents covering Gimoti, U.S. Patent Nos. 8,334,281, expiration date May 16, 2030; and 11,02,0361, expiration date December 22, 2029. These patents are listed in FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, for Gimoti. The certifications allege these patents are invalid or will not be infringed by the manufacture, use or sale of Teva's metoclopramide hydrochloride nasal spray eq. 15 mg base/spray. In April 2022, the Company initiated litigation in the United States District Court for the District of New Jersey, alleging that Teva infringes the patents covering Gimoti. Teva has denied all material allegations and asserted counterclaims of non-infringement and invalidity. The Company has not recorded any loss in connection with this matter because it believes that a loss is neither probable nor estimable at this time.

4. Technology Acquisition Agreement

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

The remaining \$47 million in milestone payments depend on Gimoti's commercial success. The Company is required to pay Mallinckrodt a low single digit royalty percentage on net sales of Gimoti. As of September 30, 2022, the Company has paid Mallinckrodt approximately \$101,000 in royalties on net sales of Gimoti. The Company's obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2030, subject to possible extension should any additional, later expiring, licensed patents be granted.

5. Stockholders' Equity

Sale of Common Stock in Public Offering

In January 2021, the Company completed the sale of 479,166 shares of its common stock in an underwritten public offering led by Laidlaw & Company (UK) Ltd. The price to the public in this offering was \$30.00 per share resulting in gross proceeds to the Company of approximately \$14.4 million. After deducting underwriting discounts and commissions and offering expenses paid by the Company, the net proceeds to the Company raised from this offering were approximately \$13.1 million.

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 included 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”). Effective January 6, 2021, the Company terminated the FBR Sales Agreement. As a result, there were no shares sold under the FBR Sales Agreement during 2021.

In December 2020, the Company filed a new shelf registration statement with the SEC on Form S-3, or the replacement shelf registration statement. The replacement shelf registration statement replaced the registration statement on Form S-3 the Company originally filed with the SEC in November 2017, which registration statement expired in December 2020. The replacement shelf registration was declared effective by the SEC on January 6, 2021. In December 2020, the Company also entered into a new At Market Issuance Sales Agreement (the “ATM Sales Agreement”), with FBR and H.C. Wainwright & Co. (together with FBR, the “Sales Agents”), pursuant to which the Company may sell from time to time, at its option, up to an aggregate of \$30 million worth of shares of the Company’s common stock through the Sales Agents. The ATM Sales Agreement provides, among other things, that sales under the ATM Sales Agreement will be made pursuant to the registration statement, including the base prospectus filed as part of such registration statement. During the third quarter of 2021, the Company sold 18,091 shares of common stock at a weighted-average price per share of \$17.64 pursuant to the ATM Sales Agreement and received proceeds of approximately \$313,000, net of commissions and fees. In February 2022, the Company sold 21,783 shares of common stock at a weighted-average price per share of \$8.04 pursuant to the ATM Sales Agreement and received proceeds of approximately \$172,000, net of commissions and fees. In April 2022, the Company sold 599,914 shares of common stock at a weighted-average price per share of \$12.12 pursuant to the ATM Sales Agreement and received proceeds of approximately \$7.1 million, net of commissions and fees.

Future sales under the ATM Sales Agreement 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 the Sales Agents 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 ATM Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to the Sales Agents under the ATM Sales Agreement. Furthermore, each of the Sales Agents is permitted to terminate the ATM Sales Agreement with respect to itself 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 shares available for sale pursuant to the ATM Sales Agreement.

Warrants

The Company has issued warrants to purchase common stock to banks that have previously loaned funds to the Company, as well as to representatives of the underwriters of the Company’s public offerings and certain of their affiliates.

During 2021, there were no warrants exercised and warrants to purchase 13,517 shares of common stock expired. During the nine months ended September 30, 2022, there were no warrants exercised and warrants to purchase 139,972 shares of common stock expired. At September 30, 2022, there were no warrants outstanding to purchase shares of common stock. At December 31, 2021, there were warrants outstanding to purchase 139,972 shares of common stock with a weighted average exercise price of \$34.80.

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 nine months ended September 30, 2022 and 2021, the Company granted stock options to purchase 78,247 and 140,167 shares of the Company’s common stock, respectively. 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 assumptions for option grants during the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,	
	2022	2021
Common Stock Options		
Risk free interest rate	1.67% - 3.55%	0.57% - 1.08%
Expected option term	5.5 - 6.02 Years	5.5 - 6.0 years
Expected volatility of common stock	97.04% - 113.23%	103.45%-107.53%
Expected dividend yield	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 assumptions for ESPP shares to be purchased during the three and nine months ended September 30, 2022 and 2021:

	<u>Three and Nine Months Ended September 30, 2022</u>	<u>Three and Nine Months Ended September 30, 2021</u>
Employee Stock Purchase Plan		
Risk free interest rate	—	0.13%
Expected term	—	0.5 years
Expected volatility of common stock	—	111.98%
Expected dividend yield	—	0.0%

There were no employee withholdings to purchase shares during the six-month purchase period beginning March 1, 2022 and September 1, 2022.

The Company recognized stock-based compensation expense to employees and directors in its research and development and its selling, general and administrative functions during the three and nine months ended September 30, 2022 and 2021 as follows:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Research and development	\$ 1,897	\$ 7,310	\$ 7,505	\$ 99,510
Selling, general and administrative	353,855	456,685	1,096,232	1,325,244
Total stock-based compensation expense	<u>\$ 355,752</u>	<u>\$ 463,995</u>	<u>\$ 1,103,737</u>	<u>\$ 1,424,754</u>

As of September 30, 2022, there was approximately \$2.2 million of unrecognized compensation costs related to outstanding employee and board of director options, which are expected to be recognized over a weighted-average period of 1.34 years.

6. Commercial Services and Loan Agreements with Eversana

In January 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 commercializes and distributes Gimoti in the United States. Eversana also manages the marketing of Gimoti to targeted health care providers, as well as the sales and distribution of Gimoti in 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. For the three months ended September 30, 2022 and 2021, approximately \$672,000 and \$753,000 of Eversana profit sharing costs were included as selling, general and administrative costs, respectively. For the nine months ended September 30, 2022 and 2021, approximately \$1,387,000 and \$1,022,000 of Eversana profit sharing costs were included as selling, general and administrative costs, respectively. As of September 30, 2022, unreimbursed commercialization costs to Eversana were approximately \$43.1 million. Such costs will generally be payable only as net product profits are recognized. 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. On February 1, 2022, the Eversana Agreement was amended (the “Amended Eversana Agreement”) to extend the term from June 19, 2025 (five years from the date the Food & Drug Administration approved the Gimoti new drug application) to December 31, 2026, unless terminated earlier pursuant to its terms. This amendment also increased the percentage of net product profit retained by the Company and increased the proportion of costs that are reimbursed to Eversana to the extent Eversana has accumulated unreimbursed costs.

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; if the Company discontinues the development or production of Gimoti; if the net profit is negative for any two consecutive calendar quarters beginning with the first full calendar quarter 24 months following commercial launch; if the cumulative net product profits fail to reach certain thresholds in the first three years following 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 Amended Eversana Agreement upon a change of control of the Company's ownership. In the event that the Company initiates such termination, the Company shall pay to Eversana a one-time payment equal to all of Eversana's unreimbursed cost plus a portion of Eversana's commercialization costs incurred in the 12 months prior to termination. 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. If Eversana terminates the agreement due to an uncured material breach by the Company, or if the Company terminates the Eversana Agreement in certain circumstances, the Company has agreed to reimburse Eversana for its unreimbursed commercialization costs for the prior twelve-month period and certain other costs. 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 have entered into the Eversana Credit Facility, pursuant to which Eversana has agreed to provide a revolving Credit Facility of up to \$5 million to the Company upon FDA approval of the Gimoti NDA under certain customary conditions. The Eversana Credit Facility terminates on June 25, 2025, unless terminated earlier pursuant to its terms. The Eversana Credit Facility is secured by all of the Company's personal property other than the Company's intellectual property. Under the terms of the Eversana Credit Facility, the Company cannot grant an interest in the Company's 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. In 2020 the Company borrowed \$5 million under 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.

On November 3, 2022, we and Eversana entered into Amendment No. 2 (the "Amendment") to the Eversana Agreement. The Amendment provides that the preexisting rights of both parties to terminate the commercial services agreement within 30 days of the first three annual anniversaries of commercial launch, if net sales of Gimoti did not meet certain annual thresholds, would be modified solely for 2022 such that either party can terminate by written notice to the other party by November 30, 2022.

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

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2021 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 8, 2022. 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, 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 commercial success, the potential to develop future product candidates, plans and objectives of management for future operations, future results of current and anticipated products and the impact of the 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 other trademarks, including GIMOTI and EvokeAssist, 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. In June 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 launched commercial sales of Gimoti in the United States in October 2020 through our commercial partner Eversana.

Diabetic gastroparesis is a GI disorder affecting millions of patients worldwide, in which food in an individual’s stomach takes too long to empty resulting in a variety of serious GI symptoms and systemic metabolic complications. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications.

In January 2020, we entered into a commercial services agreement with Eversana, or the Eversana Agreement, for the commercialization of Gimoti. Pursuant to the Eversana Agreement, Eversana commercializes and distributes Gimoti in the United States. Eversana also manages the marketing of Gimoti to targeted health care providers, as well as the sales and distribution of Gimoti in the United States. Eversana also provided a \$5 million revolving credit facility, or the Eversana Credit Facility, that became available upon FDA approval of the Gimoti NDA. In 2020 we borrowed \$5 million under the Eversana Credit Facility. On February 1, 2022, the Eversana Agreement was amended (the “Amended Eversana Agreement”) to extend the term from June 19, 2025 (five years from the date the FDA approved the Gimoti NDA) to December 31, 2026, unless terminated earlier pursuant to its terms. This amendment also increased the percentage of net product profit retained by us and increased the proportion of costs that are reimbursed to Eversana to the extent Eversana has accumulated unreimbursed costs. We further amended the Eversana Agreement in November 2022 to provide the

preexisting rights of both parties to terminate the agreement within 30 days of the first three annual anniversaries of commercial launch, if net sales of Gimoti did not meet certain annual thresholds, would be modified solely for 2022 such that either party can terminate the agreement by written notice to the other party by November 30, 2022.

We have primarily funded our operations through the sale of our convertible preferred stock prior to our initial public offering in September 2013, borrowings from loans and the sale of shares of our common stock on the Nasdaq Capital Market. We launched commercial sales of Gimoti in late October 2020 with Eversana and, to date, have generated modest sales, which we believe is partly because the launch occurred during the COVID-19 pandemic.

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, pre-commercial and commercialization activities, and other general and administrative costs associated with our operations. We expect to continue to incur operating losses until revenues from sales of Gimoti exceed our expenses, if ever. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

As of September 30, 2022, we had cash and cash equivalents of approximately \$12.4 million. Current cash on hand is intended to fund commercialization activities for Gimoti, including manufacturing Gimoti, conducting the post-marketing commitment single dose pharmacokinetics, or PK, clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti and any additional development activities should we seek additional indications, protecting our intellectual property portfolio and for other general and administrative costs to support 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 as of September 30, 2022, as well as cash flows from future net sales of Gimoti, will be sufficient to fund our operations into the second quarter of 2023. This period could be shortened if there are any significant increases in planned spending other than anticipated. We anticipate that we will 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 or identify and execute on other development or strategic alternatives for Gimoti or our company, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our securities.

Impact of COVID-19

We began our commercial sales of Gimoti with Eversana in October 2020. Due to the COVID-19 pandemic, we have experienced disruptions to our sales activities, including our efforts to reach physicians and customers. For example, Eversana's commercialization efforts at the time we launched Gimoti were adversely affected by operational restrictions imposed on its sales force from quarantines, travel restrictions and bans, and other governmental restrictions related to COVID-19. As a result of these restrictions, their sales force was restricted from conducting in-person interactions with certain physicians and customers and was restricted to conducting Gimoti educational and promotional activities virtually in certain circumstances, which impacted Eversana's ability to more actively market Gimoti. Starting in the fourth quarter of 2021, certain physician offices began to allow more frequent in-person interactions, which has increased the educational and promotional activities of the sales force. We anticipate that we and Eversana will continue to be impacted by the COVID-19 pandemic to some extent.

The COVID-19 pandemic has not significantly disrupted the operations of our third-party suppliers and manufacturers or delayed our manufacturing timelines of Gimoti, but may negatively impact our ability to successfully commercialize Gimoti and generate product sales in the future. 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 future business and financial condition, including impairing our ability to raise capital when needed.

In March 2020, the Coronavirus Aid, Relief, and Economic Security, or CARES, Act was enacted in response to the COVID-19 pandemic. 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 CARES Act. On May 1, 2020, we received the loan proceeds of approximately \$104,000. In January 2021, we received notice that our loan and accrued interest were forgiven by the SBA.

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 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, we would be required to make a single \$5 million payment on the one-year anniversary after we receive FDA approval to market Gimoti. At the time of the

Gimoti NDA approval by FDA, we recorded the \$5 million payable owed to Mallinckrodt, along with a \$5 million research and development expense. The \$5 million milestone payment was paid in July 2021.

The remaining \$47 million in milestone payments depend on Gimoti's commercial success. We are also required to pay to Mallinckrodt a low single digit royalty percentage on net sales of Gimoti. As of September 30, 2022, we have paid Mallinckrodt approximately \$101,000 for royalties on net sales of Gimoti. Our obligation to pay such royalties will terminate upon the expiration of the last patent right covering Gimoti, which is expected to occur in 2030, subject to possible extension should any additional, later expiring, licensed patents be granted.

Financial Operations Overview

Revenue Recognition

Our ability to generate revenue and become profitable depends on our ability to successfully commercialize Gimoti, which we launched in the United States through prescription in October 2020 through our commercial partner Eversana. If we or Eversana fail to successfully launch Gimoti and grow and maintain sales, we may never generate significant revenues and our results of operations and financial position will be adversely affected.

In accordance with Accounting Standards Codification, or ASC, 606, *Revenue from Contracts with Customers*, we recognize revenue when a customer obtains control of promised goods in an amount that reflects the consideration we expect to receive in exchange for the goods provided. Customer control is determined upon the customer's physical receipt of the product. To determine revenue recognition for arrangements within the scope of ASC 606, we perform the following five steps: identify the contracts with the customer; identify the performance obligations in the contract; determine the transaction price; allocate the transaction price to the performance obligations in the contract; and recognize revenue when (or as) it satisfies a performance obligation. At contract inception, we assess the goods promised within each contract and determine those that are performance obligations and assess whether each promised good is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when the customer obtains control of the product.

Product sales are recorded at the transaction price, which may include variable considerations for co-payment assistance to commercially insured patients meeting certain eligibility requirements, as well as to uninsured patients. Co-payment assistance is recorded as an offset to gross revenue at the time revenue from the product sale is recognized based on expected and actual program participation.

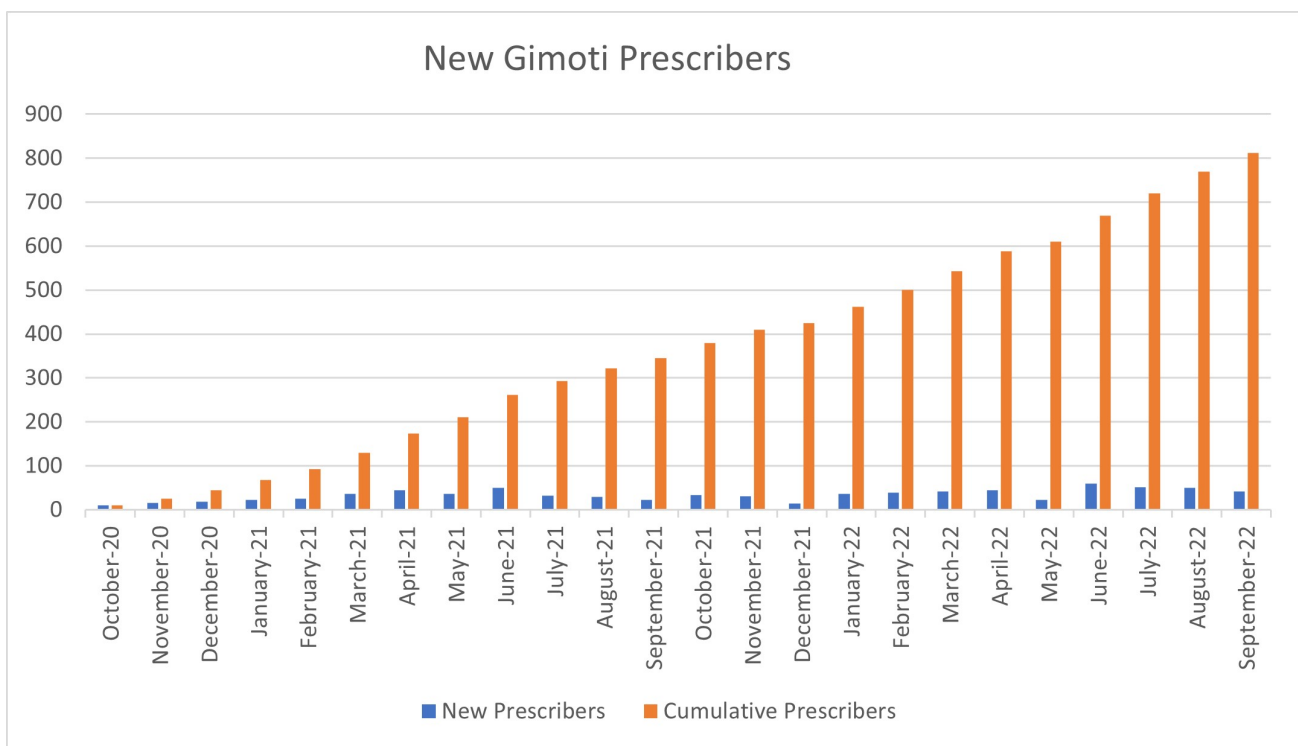
Co-pay liabilities are estimated using prescribing data available from customers. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Liabilities for co-pay assistance are classified as accounts payable and accrued expenses in the balance sheets.

Sales of Gimoti Metrics

Gimoti prescription revenues continue to increase on several metrics. Net product sales during the third quarter of 2022 were approximately \$832,000 compared to net product sales of approximately \$462,000 during the second quarter of 2022, an increase of 80%. vitaCare Prescription Services, or vitaCare, the pilot program that began in February 2022, is now the prescription intake system used for Gimoti. vitaCare is a technology and services platform that helps physicians electronically prescribe Gimoti and helps patients navigate key access and adherence barriers for brand medications. Specifically, vitaCare helps patients understand coverage and identify available savings opportunities, and facilitates communications between providers and payors. The platform also offers a seamless path for filling a prescription. In April 2022, GoodRx announced the completion of their previously announced acquisition of vitaCare.

There were approximately 800 new inbound prescriptions into the vitaCare reimbursement center during the quarter ended September 30, 2022, a 32% increase compared to the prior quarter. Patients that have an opportunity to refill the product (that is, patients who have completed their current supply and have additional refills on their prescription) received a refill approximately 67% of the time since the launch of Gimoti. We believe some patients choose not to refill their prescriptions due to remission of symptoms. Cumulatively, new prescribing physicians increased 13% during the third quarter.



The vitaCare team has been able to access the Medicare and Medicaid systems to allow for reimbursement submission of products for patients seeking treatment. For the quarter ended September 30, 2022, these government programs made up approximately 41% of the filled prescriptions for Gimoti. Through September 30, 2022, the patients have been mostly between the ages of 31-65. The vast majority of patients are female and were being treated by a gastroenterologist.

The feedback from the sales organization continues to be positive with regard to physician interest. Although many target physician offices have allowed face to face visits by sales team members, there are offices that continue to not allow face to face meetings. However, when meetings with gastroenterology teams do occur, they generally generate prescriptions and fills. Furthermore, we have detected a pattern within larger gastroenterology teams that the first physician adopting the use of Gimoti has led other physicians within the same practice to begin prescribing Gimoti as well. These market experiences follow the recently conducted market research announced in December 2021, which indicated, among other positive trends and benefits, that 92% of target gastroenterologists compared to 79% in a prior market research study, and 86-100% of non-target gastroenterologists and 89% of all respondents intend to prescribe Gimoti.

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;
- 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. Since FDA approval of Gimoti in June 2020, research and development costs have decreased and shifted to commercialization and selling costs. In 2021, we initiated planning, and are in discussion with FDA related to the design, for an FDA post-marketing commitment single dose PK clinical trial of Gimoti to characterize dose proportionality of a lower dose 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 this trial, or the regulatory review of such lower dosage of Gimoti, though such costs may be significant and will substantially increase research and development expenses once this trial is initiated. We may also incur additional costs to the extent we pursue additional clinical trials to expand the indication of Gimoti. 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 patient follow-up.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation. Other selling, 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 selling, general and administrative expenses will increase in the future as we continue to progress with the commercialization of Gimoti and we reimburse Eversana from the net profits attained from the sales of Gimoti.

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.

There have been no new or significant changes to our critical accounting policies and estimates discussed 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, 2021, filed with the SEC on March 8, 2022.

Results of Operations

Comparison of Three Months Ended September 30, 2022 and 2021

The following table summarizes the results of our operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		(Decrease)
	2022	2021	
Net product sales	\$ 832,100	\$ 930,449	\$ (98,349)
Research and development expenses	\$ 40,388	\$ 81,699	\$ (41,311)
Selling, general and administrative expenses	\$ 2,614,488	\$ 2,635,161	\$ (20,673)

Net Product Sales. Excluding \$683,000 in sales made to a third party for research and development purposes in the third quarter of 2021, net product sales for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 increased by approximately \$585,000. The increase in sales was primarily driven by increased educational and promotional activities of the Eversana sales force during the three months ended September 30, 2022.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 decreased by approximately \$41,000. During 2022 and 2021, we incurred expenses for ongoing stability testing of batches of Gimoti manufactured prior to receipt of FDA approval of the Gimoti NDA in June 2020.

Costs incurred during the three months ended September 30, 2022 included approximately \$34,000 related to stability testing and approximately \$6,000 for wages, taxes and employee insurance, including approximately \$2,000 of stock-based compensation expense.

Costs incurred during the three months ended September 30, 2021 included approximately \$62,000 related to manufacturing and \$19,000 for wages, taxes and employee insurance, including approximately \$7,000 of stock-based compensation expense.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 decreased by approximately \$21,000. Costs incurred during the three months ended September 30, 2022 primarily included approximately \$1.0 million for wages, taxes and employee insurance, including approximately \$354,000 of stock-based compensation expense, approximately \$904,000 for marketing, royalties and Eversana profit sharing, approximately \$602,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company, and approximately \$48,000 for facility-related expenses. Costs incurred during the three months ended September 30, 2021 primarily included approximately \$1.1 million for wages, taxes and employee insurance, including approximately \$457,000 of stock-based compensation expense, approximately \$924,000 for marketing, royalties and Eversana profit sharing, and approximately \$543,000 for legal, accounting, directors and officers liability insurance and other costs associated with being a public company.

Comparison of Nine Months Ended September 30, 2022 and 2021

The following table summarizes the results of our operations for the Nine Months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Increase/ (Decrease)
	2022	2021	
Net product sales	\$ 1,712,275	\$ 1,257,505	\$ 454,770
Research and development expenses	\$ 273,582	\$ 554,753	\$ (281,171)
Selling, general and administrative expenses	\$ 7,334,738	\$ 7,115,605	\$ 219,133

Net Product Sales. Excluding \$683,000 in sales made to a third party for research and development purposes in the third quarter of 2021, net product sales for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 increased by approximately \$1.1 million. The increase in sales was primarily driven by increased educational and promotional activities of the Eversana sales force during the nine months ended September 30, 2022.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 decreased by approximately \$281,000. During 2022 and 2021, we incurred expenses for ongoing stability testing of batches of Gimoti manufactured prior to receipt of FDA approval of the Gimoti NDA in June 2020, as well as preparing for a post-marketing commitment to conduct a single dose PK clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti, including the manufacture of clinical trial material.

Costs incurred during the nine months ended September 30, 2022 included approximately \$248,000 for manufacturing and \$25,000 for wages, taxes and employee insurance, including approximately \$8,000 of stock-based compensation expense. Cost incurred during the nine months ended September 30, 2021, included approximately \$260,000 for manufacturing and \$252,000 for wages, taxes and employee insurance, including approximately \$100,000 of stock-based compensation expense.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 increased by approximately \$219,000. Costs incurred during the nine months ended September 30, 2022 primarily included approximately \$3.1 million for wages, taxes and employee insurance, including approximately \$1.1 million of stock-based compensation expense, approximately \$2.1 million for marketing, royalties and Eversana profit sharing, approximately \$1.9 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company, and approximately \$138,000 for facility-related expenses. Costs incurred during the nine months ended September 30, 2021 primarily included approximately \$3.3 million for wages, taxes and employee insurance, including approximately \$1.3 million of stock-based compensation expense, approximately \$1.9 million for legal, accounting, directors and officers liability insurance and other costs associated with being a public company, approximately \$1.5 million for marketing, royalties and Eversana profit sharing, and approximately \$118,000 for facility-related expenses.

Liquidity and Capital Resources

In November 2017, we filed a shelf registration statement with the SEC on Form S-3. The shelf registration statement included 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. Effective January 6, 2021, we terminated the FBR Sales Agreement. As a result, there were no shares sold under the FBR Sales Agreement during 2021.

In December 2020, we filed a new shelf registration statement with the SEC on Form S-3, or the replacement shelf registration statement. The replacement shelf registration statement replaced the registration statement on Form S-3 we originally filed with the SEC in November 2017, which registration statement expired in December 2020. The replacement shelf registration was declared effective by the SEC on January 6, 2021. In December 2020, we also entered into the ATM Sales Agreement with FBR and H.C. Wainwright & Co., LLC, or the Sales Agents, pursuant to which we may sell from time to time, at our option, up to an aggregate of \$30 million worth of shares of our common stock through the Sales Agents. The ATM Sales Agreement provides, among other things, that

sales under the ATM Sales Agreement will be made pursuant to the registration statement, including the base prospectus filed as part of such registration statement. During 2021, we sold 18,091 shares of common stock at a weighted-average price per share of \$17.64 pursuant to the ATM Sales Agreement and received proceeds of approximately \$313,000, net of commissions and fees. During the nine months ended September 30, 2022, we sold 621,697 shares of common stock at a weighted-average price per share of \$11.97 pursuant to the ATM Sales Agreement and received proceeds of approximately \$7.3 million, net of commissions and fees.

Under current SEC regulations, if at the time we file our Annual Report on Form 10-K our public float is less than \$75 million, and for so long as our public float remains less than \$75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float, which is referred to as the baby shelf rules.

At the time we filed our Annual Report on Form 10-K on March 8, 2022, our public float was less than \$75 million. As a result of our public float being below \$75 million, we will be limited by the baby shelf rules until such time as our public float exceeds \$75 million, which means we only have the capacity to sell shares up to one-third of our public float under shelf registration statements in any twelve-month period. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statement will also decrease. As of November 4, 2022, there was no capacity to issue additional shares of common stock pursuant to the ATM Sales Agreement. We will remain constrained by the baby shelf rules under our Form S-3 shelf registration statement until such time as our public float exceeds \$75 million, at which time the number of securities we may sell under a Form S-3 registration statement will no longer be limited by the baby shelf rules.

Future sales under the ATM 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 the Sales Agents will be successful in consummating future sales based on prevailing market conditions or in the quantities or at the prices that we deem appropriate.

In addition, we will not be able to make future sales of common stock pursuant to the ATM Sales Agreement unless certain conditions are met, which include the accuracy of representations and warranties made to the Sales Agents under the ATM Sales Agreement. Furthermore, each of the Sales Agents is permitted to terminate the ATM Sales Agreement with respect to itself 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 shares available for sale pursuant to the ATM 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 our personal property other than our 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. In 2020 we borrowed \$5 million from the Eversana Credit Facility.

In January 2021, we completed the sale of 479,166 shares of our common stock in an underwritten public offering led by Laidlaw & Company (UK) Ltd. The price to the public in this offering was \$30.00 per share resulting in gross proceeds to us of approximately \$14.4 million. After deducting underwriting discounts and commissions, and offering expenses paid by us, the net proceeds to us raised from this offering were approximately \$13.1 million.

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 issuance 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 by our independent registered accounting firm 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 cash and cash equivalents as of September 30, 2022 of approximately \$12.4 million, as well as future cash flows from net sales of Gimoti, will be sufficient to fund our operations into the second quarter of 2023. This period could be shortened if there are any significant increases in planned spending other than anticipated. We anticipate we will 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 or identify and execute on other development or strategic alternatives for Gimoti or our company, we will be required to curtail all of our activities and may be required to liquidate, dissolve or otherwise wind down our operations. Any of these events could result in a complete loss of your investment in our securities.

These estimates of cash runway could be shortened if there are any significant increases in planned spending on commercialization activities, including for marketing and manufacturing of Gimoti, and our selling, general and administrative costs to support operations. There is no assurance that other financing will be available when needed to allow us to continue as a going concern. The perception that

we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

On December 29, 2021, we received a letter from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq Capital Market.

In accordance with Nasdaq listing rules, we were provided an initial period of 180 calendar days, or until June 27, 2022, to regain compliance. The letter states that Nasdaq will provide written notification that we have achieved compliance with its rules if at any time before June 27, 2022, the bid price of our common stock closes at \$1.00 per share or more for a minimum of ten consecutive business days. The Nasdaq letter had no immediate effect on the listing or trading of our common stock and the common stock continued to trade on The Nasdaq Capital Market.

On April 27, 2022, our stockholders granted the board of directors the authority to effect a reverse stock split of our outstanding common stock. On May 23, 2022, we effected a 1-for-12 reverse stock split of the shares of our common stock, or the Reverse Stock Split. The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. All of our issued and outstanding common stock, warrants to purchase common stock, and options to purchase common stock have been adjusted to reflect the Reverse Stock Split.

On June 7, 2022, we received notice from Nasdaq stating that the closing price of our common stock has been \$1.00 per share or greater for the prior ten consecutive business days and that we had regained compliance with the minimum \$1.00 per share requirement.

We expect to continue to incur expenses as we:

- continue the commercial activities for Gimoti;
- manufacture Gimoti;
- conduct the post-marketing commitment single dose PK clinical trial of Gimoti and any additional development activities should we seek additional indications;
- maintain, expand and protect our intellectual property portfolio; and
- continue to fund the accounting, legal, insurance and other costs associated with being a public company.

The following table summarizes our cash flows for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Increase/ (Decrease)
	2022	2021	
Net cash used in operating activities	\$ (4,089,662)	\$ (10,355,746)	\$ 6,266,084
Net cash provided by financing activities	\$ 7,294,976	\$ 13,428,715	\$ (6,133,739)
Net increase (decrease) in cash and cash equivalents	\$ 3,205,314	\$ 3,072,969	\$ 132,345

Operating Activities. The primary use of our cash has been to fund our clinical research, prepare our NDA, manufacture Gimoti, prepare for and begin commercial sales of Gimoti, and other general operations. The cash used in operating activities during the nine months ended September 30, 2022 and 2021 was primarily related to commercialization activities for Gimoti and other general operational activities. We expect that cash used in operating activities will increase during the remainder of 2022 due to commercialization activities, including manufacturing of Gimoti, and the planned post-marketing commitment to conduct a single dose PK clinical trial of Gimoti to characterize dose proportionality of a lower dose strength of Gimoti.

Financing Activities. During the nine months ended September 30, 2022, we received net proceeds of approximately \$7.3 million from the sale of 621,697 shares of common stock pursuant to the ATM Sales Agreement. During the nine months ended September 30, 2021 we received net proceeds of approximately \$13.1 million from the sale of 479,166 shares of common stock pursuant to an underwritten public offering, \$313,000 from the sale of 18,083 shares of common stock pursuant to the ATM Sales Agreement, and approximately \$45,000 from the exercise of stock options to purchase 5,618 shares of common stock.

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 approved earlier 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 to conduct a single dose PK clinical 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 September 30, 2022, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

Contractual Obligations and Commitments

There were no material changes outside the ordinary course of our business during the nine months ended September 30, 2022 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, 2021, filed with the SEC on March 8, 2022.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

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 September 30, 2022 we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Business Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Business Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2022.

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 September 30, 2022 that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On February 25, 2022, we received a letter notifying us that Teva submitted to FDA an abbreviated new drug application, or ANDA, for a generic version of Gimoti (metoclopramide hydrochloride) nasal spray eq. 15 mg base/spray that contains Paragraph IV certifications with respect to two of our patents covering Gimoti, U.S. Patent Nos. 8,334,281, expiration date May 16, 2030; and 11,02,0361, expiration date December 22, 2029. These patents are listed in FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, for Gimoti. The certifications allege these patents are invalid or

will not be infringed by the manufacture, use or sale of Teva's metoclopramide hydrochloride nasal spray eq. 15 mg base/spray. In April 2022, we initiated litigation in the United States District Court for the District of New Jersey alleging that Teva infringes the patents covering Gimoti. Teva has denied all material allegations and asserted counterclaims of non-infringement and invalidity.

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, 2021, filed with the SEC on March 8, 2022 other than as follows:

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 cash and cash equivalents as of September 30, 2022 of approximately \$12.4 million, as well as cash flows from net sales of Gimoti, will be sufficient to fund our operations into the second quarter of 2023. This period could be shortened if there are any significant increases in planned spending other than anticipated. We anticipate that we will be required to raise additional funds through debt, equity or other forms of financing, such as potential collaboration arrangements, to fund future operations and continue as a going concern. There can be no assurance that 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 commercial success of Gimoti;
- the repayment of unreimbursed commercialization costs to Eversana, approximately \$43.1 million as of September 30, 2022, to be payable only as net product profits are recognized;
- the costs of commercialization activities, including costs associated with commercial manufacturing;
- our ability to maintain our existing commercial services agreement with Eversana or, if it is terminated or we otherwise elect to do so, retain an alternative organization, or develop our own sales and marketing capability, to commercialize and distribute Gimoti;
- competition with well-established products approved earlier 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 PK 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. If adequate funds are not available to us, we may not be able to make scheduled debt payments on a timely basis, or at all, and may be required to delay, limit, reduce or cease our operations.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On November 3, 2022, we and Eversana entered into Amendment No. 2 (the "Amendment") to the Commercial Services Agreement, dated January 21, 2020, as amended, by and between the company and Eversana, or the Commercial Services Agreement. The Amendment provides that the preexisting rights of both parties to terminate the Commercial Services Agreement within 30 days of the first three annual anniversaries of commercial launch, if net sales of Gimoti did not meet certain annual thresholds, would be modified solely for 2022 such that either party can terminate the Commercial Services Agreement by written notice to the other party by November 30, 2022.

The foregoing description of the terms of the Amendment does not purport to be complete, and is qualified in its entirety by reference to the complete copy of the Amendment, which is attached as Exhibit 10.1 herewith and is incorporated by reference herein.

Item 6. Exhibits**Index to Exhibits**

Exhibit Number	Description of Exhibit
3.1 (1)	Amended and Restated Certificate of Incorporation of the Company, as amended
3.2 (1)	Amended and Restated Bylaws of the Company
4.1 (2)	Form of the Company's Common Stock Certificate
10.1(†)	Amendment No. 2 to the Commercial Services Agreement, dated as of November 3, 2022, between the Company and Eversana Life Sciences Services, LLC
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	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

(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.

(†) Certain portions of this exhibit have been omitted and are subject to confidential treatment.

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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

Evoke Pharma, Inc.

Date: November 9, 2022

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

Date: November 9, 2022

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

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE EVOKE PHARMA, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO EVOKE PHARMA, INC. IF PUBLICLY DISCLOSED.

AMENDMENT NO. 2 TO THE COMMERCIAL SERVICES AGREEMENT

THIS AMENDMENT NO. 2 TO MASTER SERVICES AGREEMENT (this “Amendment”) is entered into as of November 3, 2022 (the “Amendment Effective Date”), by and between **Evoke Pharma, Inc.**, a corporation with its principal offices located at 420 Stevens Avenue, Suite 370, Solana Beach, CA 92075 (“**Evoke**”) and **EVERSANA Life Science Services, LLC**, a Wisconsin limited liability company, with its principal offices located at 190 North Milwaukee Street, Milwaukee, Wisconsin 53202 (“**Eversana**”).

BACKGROUND

WHEREAS, Evoke and Eversana entered into a Commercial Services Agreement, effective January 21, 2020 (the “Agreement”);

WHEREAS, Evoke and Eversana desire to revise the Agreement in accordance with the terms and conditions contained herein;

WHEREAS, the Agreement as amended is in full force and effect; and

WHEREAS, except as may be expressly provided otherwise in this Amendment, capitalized terms in this Amendment have the meaning set forth in the Agreement.

NOW, THEREFORE, in consideration of the mutual promises hereinafter set forth, and intending to be legally bound hereby, Evoke and Eversana agree as follows:

1. Section 14.2(c) of the Agreement is hereby deleted in its entirety and replaced with the following:

“**Termination for Revenue Shortfall.** After each anniversary of Commercial Launch, either Party shall be entitled to terminate the Agreement by providing the other party with thirty (30) days written notice if cumulative Net Sales have not exceeded the amount set forth below by the date set forth below (the “**Minimum Net Revenue**” or “**MNR**”), so long as such termination right is exercised within thirty (30) days of the dates set forth below:

- i. October 5, 2021 – MNR is [***] dollars (\$[***]);
- ii. October 13, 2022 – MNR is [***] dollars (\$[***]); and
- iii. October 5, 2023 – MNR is [***] dollars (\$[***]).”

Notwithstanding anything to the contrary herein, the time period for providing a written notice of Termination for Revenue Shortfall in year 2022 pursuant to the trigger event noted in 14.2(c)ii above shall end at midnight on November 30, 2022, to allow the parties

additional time to work through the continued terms of their partnership.

2. Entire Amendment. This Amendment sets forth the entire agreement of the Parties with respect to the subject matter set forth herein and may not be modified other than by an agreement in writing signed by the Parties hereto or their respective successors in interest.
3. Acknowledgment. The Parties hereto each acknowledge that except as expressly modified by this Amendment, all the terms and conditions of the Agreement remain unchanged and are in full force and effect and enforceable in accordance with their terms. In the event of a conflict between the Agreement and this Amendment, the terms and provisions of this Amendment control.
4. Counterparts; Electronic Signatures. The Parties acknowledge and agree that this Amendment may be signed (a) in any number of counterparts, which may be transmitted by facsimile or PDF, all of which taken together constitutes one and the same instrument; and (b) electronically using an e-signature program or service; and (c) for all purposes, including but not limited to admissibility, enforceability and validity, treat the counterpart facsimiles or PDFs and electronic signatures as if those documents were signed by hand and the electronic signatures were hand-written signatures.

(Signature Page Follows)

IN WITNESS WHEREOF, the undersigned, intending to be legally bound, has duly executed this Agreement as of the date first above written.

EVOKE PHARMA, INC.	EVERSANA LIFE SCIENCES SERVICES, LLC
By: /s/ David A. Gonyer	By: /s/ Gregory Skalicky
Name: David A. Gonyer	Name: Gregory Skalicky
Title: President, Chief Executive Officer and Director (principal executive officer)	Title: Chief Revenue 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: November 9, 2022

/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: November 9, 2022

/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 September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David A. Gonyer, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: November 9, 2022

/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 September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew J. D'Onofrio, Executive Vice President, Chief Business Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: November 9, 2022

/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.
