

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 10, 2022

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36075
(Commission
File Number)

20-8447886
(IRS Employer
Identification No.)

420 Stevens Avenue, Suite 370
Solana Beach, California
(Address of Principal Executive Offices)

92075
(Zip Code)

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

(Former Name or Former Address, if Changed Since Last Report.)

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

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

Trading symbol
EVOK

Name of each exchange on which registered
The Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2022, Evoke Pharma, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.*(d) Exhibits*

Exhibit No.	Description
99.1	Press Release issued on May 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

EVOKE PHARMA, INC.

Date: May 10, 2022

By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary



Evoked Pharma Reports First Quarter 2022 Financial Results

Several sales growth indicators increased over Q4, 2021: New Prescribers up 41%; Product delivered to patients up 39%; Net Revenue increased by 16%; Prescriptions written up 22%

SOLANA BEACH, Calif., May 10, 2022 (GLOBE NEWSWIRE – Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused primarily on treatments for gastrointestinal (GI) diseases, today announced its financial results for the first quarter ended March 31, 2022, and recent corporate developments.

“We are encouraged by the incremental improvement in net GIMOTI sales and prescriptions and continue to receive positive feedback from patients and physicians. Working closely with our strategic commercial partner, Eversana, we continue to implement and execute strategies as we seek continued improvement in the quarters ahead,” said David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. “We have achieved four consecutive quarters of increased revenue with an additional 16% this quarter, to \$418,000. In addition, the number of GIMOTI prescribers increased by approximately 41%, to 538 cumulative new healthcare providers (HCPs) through March 31, 2022. Finally, prescriptions received into our specialty pharmacies increased by 22% in the first quarter. More patients than ever – as well as their healthcare providers – are experiencing the benefits of GIMOTI’s novel nasal solution for diabetic gastroparesis.”

First Quarter 2022 Developments and Recent Progress:

GIMOTI was added to two state Medicaid Programs

- New York Medicaid; Coverage allows for more rapid utility of GIMOTI
- Texas Medicaid Preferred Drug List (PDL); Effective April 12, 2022, approximately 5 million additional patients are able to quickly access GIMOTI
- Medicaid and Medicare made up approximately 51% of the filled prescriptions for GIMOTI in the first quarter of 2022

New drug product exclusivity granted by the FDA for GIMOTI nasal spray

- Company now has Hatch-Waxman Act exclusive marketing rights for three years from approval date
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Piloted strategic collaboration with vitaCare (subsidiary of GoodRx.com)

- Quick and convenient electronic submission of prescriptions by doctors to pharmacies online
- More effective and accelerated insurance approval of prescriptions by pharmacies, state Medicaid agencies and private insurance companies
- Commercial patients may receive trial samples while awaiting insurance reimbursement

Abstract on association between tardive dyskinesia (TD) and potential risk factors accepted as poster of distinction at Digestive Disease Week (DDW) on May 21, 2022 in San Diego

- Data will update TD incidence in metoclopramide which may have been previously overestimated
- Additional medical subgroups analyzed to inform physicians of possible additional treatment factors

Extends cash runway into Q2, 2023

- ATM program accessed for additional sales runway

First Quarter 2022 Financial Review

For the first quarter of 2022, net product sales were approximately \$418,000 compared to approximately \$90,000 during the first quarter of 2021, and the net loss was approximately \$2.2 million, or \$0.07 cents per share compared with \$2.6 million, or \$0.08 per share, for the first quarter of 2021. The increase in net sales was primarily driven by increased educational and promotional activities of the Eversana sales force.

For the first quarter of 2022, selling, general and administrative expenses were approximately \$2.4 million compared with \$2.3 million for the first quarter of 2021. We expect that selling, general and administrative expenses may 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.

Total operating expenses for the first quarter of 2022 were approximately \$2.5 million compared with \$2.7 million for the same period of 2021.

As of March 31, 2022, cash and cash equivalents were approximately \$7.7 million. We also received net proceeds of approximately \$7.1 million from sales under our ATM program after March 31, 2022. We believe, based on our current operating plan, that our existing cash and cash equivalents, as well as future cash flows from net product sales of GIMOTI, will be sufficient to fund our operations into the second quarter of 2023.

About Evoke Pharma, Inc.

Evoke is a specialty pharmaceutical company focused primarily on the development of drugs to treat GI disorders and diseases. The company developed, commercialized and markets GIMOTI, a nasal spray

formulation of metoclopramide, for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adults.

Diabetic gastroparesis is a GI disorder affecting millions of patients worldwide, in which the stomach takes too long to empty its contents resulting in serious GI symptoms as well as other systemic complications. The gastric delay caused by gastroparesis can compromise absorption of orally administered medications. Prior to FDA approval to commercially market GIMOTI, metoclopramide was only available in oral and injectable formulations and remains the only drug currently approved in the United States to treat gastroparesis. Visit www.EvokePharma.com for more information.

Follow GIMOTI on Facebook: <https://www.facebook.com/GIMOTI-metoclopramide-nasal-spray-104672345100289> Follow Evoke Pharma on Facebook: <https://www.facebook.com/Evoke-Pharma-Inc-131313647029724>

Follow Evoke Pharma on LinkedIn: <https://www.linkedin.com/company/evoke-pharma/>

About Gimoti® (metoclopramide) nasal spray

GIMOTI is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

Important Safety Information

WARNING: TARDIVE DYSKINESIA

- Metoclopramide can cause tardive dyskinesia (TD), a serious movement disorder that is often irreversible. The risk of developing TD increases with duration of treatment and total cumulative dosage.
- Discontinue GIMOTI in patients who develop signs or symptoms of TD. In some patients, symptoms may lessen or resolve after metoclopramide is stopped.
- Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks because of the increased risk of developing TD with longer-term use.

GIMOTI is not recommended for use in:

- Pediatric patients due to the risk of developing tardive dyskinesia (TD) and other extrapyramidal symptoms as well as the risk of methemoglobinemia in neonates.
- Moderate or severe hepatic impairment (Child-Pugh B or C), moderate or severe renal impairment (creatinine clearance less than 60 mL/minute), and patients concurrently using strong CYP2D6 inhibitors due to the risk of increased drug exposure and adverse reactions.

GIMOTI is contraindicated:

- In patients with a history of tardive dyskinesia (TD) or a dystonic reaction to metoclopramide.
 - When stimulation of gastrointestinal motility might be dangerous (e.g., in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation).
 - In patients with pheochromocytoma or other catecholamine-releasing paragangliomas. Metoclopramide may cause a hypertensive/pheochromocytoma crisis, probably due to release of catecholamines from the tumor.
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- In patients with epilepsy. Metoclopramide may increase the frequency and severity of seizures.
- In patients with hypersensitivity to metoclopramide. Reactions have included laryngeal and glossal angioedema and bronchospasm.

Potential adverse reactions associated with metoclopramide include: Tardive dyskinesia (TD), other extrapyramidal effects (EPS), parkinsonism symptoms, motor restlessness, neuroleptic malignant syndrome (NMS), depression, suicidal ideation and suicide, hypertension, fluid retention, hyperprolactinemia, effects on the ability to drive and operate machinery. Most common adverse reactions ($\geq 5\%$) for GIMOTI are: dysgeusia, headache, and fatigue. These are not all of the possible side effects of GIMOTI. Call your doctor for medical advice about whether you should take GIMOTI and the possible risk factors and side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Safe Harbor Statement

Evoke cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. 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 negatives of these terms or other similar expressions. These statements are based on the company’s current beliefs and expectations. These forward-looking statements include statements regarding: potential future prescribing trends and sales for GIMOTI based on Evoke’s or EVERSANA’s marketing efforts; Evoke’s commercialization plans, including its plans to increase awareness of and access to GIMOTI; and Evoke’s future capital requirements. The inclusion of forward-looking statements should not be regarded as a representation by Evoke that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Evoke’s business, including, without limitation: Evoke’s and EVERSANA’s ability to successfully drive market demand for GIMOTI; Evoke’s ability to obtain additional financing as needed to support its operations; the COVID-19 pandemic may continue to disrupt Evoke’s and EVERSANA’s business operations impairing the ability to commercialize GIMOTI and Evoke’s ability to generate product revenue; Evoke’s dependence on third parties for the manufacture of GIMOTI; Evoke is entirely dependent on the success of GIMOTI; inadequate efficacy or unexpected adverse side effects relating to GIMOTI that could result in recalls or product liability claims; Evoke’s ability to maintain intellectual property protection for GIMOTI; and other risks and uncertainties detailed in Evoke’s prior press releases and in the periodic reports it files with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Evoke undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Investor Contact:

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(Financial Statements to Follow)

Evoke Pharma, Inc.		
Condensed Balance Sheets		
	March 31, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 7,701,201	\$ 9,144,710
Accounts receivable, net	418,910	295,193
Prepaid expenses	615,832	923,746
Inventory	278,776	185,534
Other current assets	11,551	11,551
Total current assets	<u>9,026,270</u>	<u>10,560,734</u>
Operating lease right-of-use asset	—	12,428
Total assets	<u><u>\$ 9,026,270</u></u>	<u><u>\$ 10,573,162</u></u>
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 944,478	\$ 874,028
Accrued compensation	412,198	519,317
Operating lease liability	—	12,428
Total current liabilities	<u>1,356,676</u>	<u>1,405,773</u>
Long-term liabilities		
Note payable	5,000,000	5,000,000
Accrued interest payable	735,583	612,295
Total long-term liabilities	<u>5,735,583</u>	<u>5,612,295</u>
Total liabilities	<u>7,092,259</u>	<u>7,018,068</u>
Stockholders' equity:		
Common stock	3,292	3,266
Additional paid-in capital	111,527,397	110,974,841
Accumulated deficit	<u>(109,596,678)</u>	<u>(107,423,013)</u>
Total stockholders' equity	<u>1,934,011</u>	<u>3,555,094</u>
Total liabilities and stockholders' (deficit) equity	<u><u>\$ 9,026,270</u></u>	<u><u>\$ 10,573,162</u></u>

Evoke Pharma, Inc.

Condensed Statements of Operations

	Three Months Ended	
	March 31,	
	2022	2021
Net product sales	\$ 418,380	\$ 90,421
Operating expenses:		
Cost of goods sold	22,760	64,751
Research and development	41,717	277,825
Selling, general and administrative	2,405,075	2,338,295
Total operating expenses	<u>2,469,552</u>	<u>2,680,871</u>
Loss from operations	(2,051,172)	(2,590,450)
Other income (expense):		
Forgiveness of paycheck protection loan and accrued interest	—	105,130
Interest income	795	3,164
Interest expense	(123,288)	(123,339)
Total other income (expense)	<u>(122,493)</u>	<u>(15,045)</u>
Net loss	<u>\$ (2,173,665)</u>	<u>\$ (2,605,495)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.08)</u>
Weighted-average shares used to compute basic and diluted net loss per share	<u>32,777,294</u>	<u>31,158,065</u>