

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 15, 2023

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)

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:

- 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))

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

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

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 15, 2023, Evoke Pharma, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2023. 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 15, 2023
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 15, 2023

By: /s/ Matthew J. D'Onofrio

Name: Matthew J. D'Onofrio

Title: President, Chief Operating Officer and Secretary



Exhibit 99.1

Evoked Pharma Reports First Quarter 2023 Financial Results

*Net product sales increased by 94% from Q1 2022
New cumulative prescribers up by 17% from Q4 2022
Doubled patient enrollment since Q1 2022; 127% increase*

SOLANA BEACH, Calif., May 15, 2023 (GLOBE NEWSWIRE) -- Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused primarily on treatments for gastrointestinal (GI) diseases with an emphasis on GIMOTI[®] (metoclopramide) nasal spray, today announced its financial results for the first quarter ended March 31, 2023, and recent corporate developments.

"We are pleased to witness a solid uptick in most categories of our sales growth indicators – net revenue, fills, cumulative prescribers and patient enrollments over the course of the first quarter of 2023. Looking back at our sales metrics in Q4 2022, we returned to normal levels of upward revenue growth and recorded \$810,000 in net product sales in Q1 2023, approximately a 2% increase from Q4 2022, and up 94% year-over-year. Our cumulative prescribers increased 17% from Q4 2022 and have now reached 1,189. Prescription fills also continue to rise with an 11% increase over the previous quarter," said David A. Gonyer, R.Ph., Evoke Pharma's CEO.

"Insights from a recent survey, market data analysis, and patient and healthcare provider anecdotes, demonstrate the need for GIMOTI in the marketplace and we believe that the incremental growth in our sales metrics confirms this sentiment. Our current sales performance coupled with the Company's recent corporate achievements particularly on the intellectual property front, we believe in the commercial success of GIMOTI while improving the quality of life for patients living with gastroparesis." concluded Mr. Gonyer.

First Quarter 2023 Developments and Recent Progress

- **Further strengthened intellectual property estate**
 - Successfully settled Teva Pharmaceuticals lawsuit with dismissal from both parties, ending Teva's attempt of a Paragraph IV ANDA certification
 - Granted new U.S. patent (No. 11,628,150) covering the nasal solution of metoclopramide and its characteristics when formulated
 - Newly listed U.S. patent (No. 11,628,150) in the U.S. Food and Drug Administration (FDA) "Orange Book"
- **Presented healthcare resource utilization real-world data analyses at leading medical meetings**
 - Data abstract suggesting that GIMOTI (nasal metoclopramide) patients experience a lower use of healthcare resources compared to patients receiving oral metoclopramide accepted and presented in DDW's distinguished plenary session

Compelling real-world data presented at Academy of Managed Care Pharmacy (AMCP) 2023 also demonstrating the mitigated use of healthcare resources amongst patients treated with GIMOTI

First Quarter 2023 Financial Review

For the first quarter of 2023, net product sales were approximately \$810,000 compared to approximately \$418,000 during the first quarter of 2022. The increase in net sales was primarily driven by increased promotional activities of the Eversana sales force and prescription management through vitaCare.

For the first quarter of 2023, selling, general and administrative expenses were approximately \$2.8 million compared to \$2.4 million for the first quarter of 2022. The increases were due to higher professional fees and reimbursement and profit-sharing activity with EVERSANA.

Total operating expenses for the first quarter of 2023 were approximately \$3.0 million compared to \$2.5 million for the same period in 2022.

As of March 31, 2023, cash and cash equivalents were approximately \$8.2 million. 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 fourth 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.

Visit www.EvokePharma.com for more information.

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Follow Evoke Pharma on Facebook

Follow Evoke Pharma on LinkedIn

Follow Evoke Pharma on Twitter

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.

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 FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Safe Harbor Statement

Invoke 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 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 change the standard of care for diabetic gastroparesis; and Evoke's future capital requirements, including whether Evoke's cash and cash equivalents and future cash flows from net product sales will be sufficient to fund its operations into the fourth quarter of 2023 . 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 & Media Contact:

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Financial Statements to Follow

Evoke Pharma, Inc.
Condensed Balance Sheet

	March 31, 2023	December 31, 2022
	(unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 8,212,804	\$ 9,843,699
Accounts receivable, net	687,302	624,832
Prepaid expenses	671,386	952,954
Inventory, net	364,867	289,378
Other current assets	11,551	11,551
Total current assets	9,947,910	11,722,414
Operating lease right-of-use asset	91,397	129,074
Total assets	\$ 10,039,307	\$ 11,851,488
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,185,925	\$ 934,312
Accrued compensation	400,251	591,158
Operating lease liability	91,397	129,074
Total current liabilities	1,677,573	1,654,544
Long-term liabilities		
Note payable	5,000,000	5,000,000
Accrued interest payable	1,235,583	1,112,295
Total long-term liabilities	6,235,583	6,112,295
Total liabilities	7,913,156	7,766,839
Stockholders' equity:		
Common stock, \$0.0001 par value; authorized shares - 50,000,000; issued and outstanding shares - 3,343,070 at March 31, 2023 and December 31, 2022, respectively	334	334
Additional paid-in capital	120,016,030	119,731,458
Accumulated deficit	(117,890,213)	(115,647,143)
Total stockholders' equity	2,126,151	4,084,649
Total liabilities and stockholders' equity	\$ 10,039,307	\$ 11,851,488

Evoke Pharma, Inc.
Condensed Statement of Operations
(unaudited)

	Three Months Ended March 31,	
	2023	2022
Net product sales	\$ 810,408	\$ 418,380
Operating expenses:		
Cost of goods sold	50,591	22,760
Research and development	66,990	41,717
Selling, general and administrative	2,847,940	2,405,075
Total operating expenses	2,965,521	2,469,552
Loss from operations	(2,155,113)	(2,051,172)
Other income (expense):		
Interest income	35,331	795
Interest expense	(123,288)	(123,288)
Total other (expense)	(87,957)	(122,493)
Net loss	\$ (2,243,070)	\$ (2,173,665)
Net loss per share of common stock, basic and diluted	\$ (0.67)	\$ (0.80)
Weighted-average shares used to compute basic and diluted net loss per share	3,343,070	2,731,440

