
**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 14, 2024

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 230
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 14, 2024, Evoke Pharma, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2024. 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 14, 2024
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 14, 2024

By: /s/ Matthew J. D'Onofrio
Name: Matthew J. D'Onofrio
Title: Chief Executive Officer and Director



Evoke Pharma Reports First Quarter 2024 Financial Results

114% year-over-year increase in net product sales

70% prescriber growth in Q1 2024 compared to Q4 2023

Growing sales metrics reaffirms company's \$14M net revenue guidance for 2024

SOLANA BEACH, Calif., May 14, 2024 (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, 2024, and recent corporate developments.

Matt D’Onofrio, CEO of Evoke Pharma commented, "The results achieved in the first quarter of 2024 reflect continued momentum with the adoption of GIMOTI. The real-world healthcare utilization data, including outcomes from over 500 patients, have consistently supported GIMOTI's efficacy for diabetic gastroparesis treatment compared to oral. Moreover, testimonials from leading physicians and the positive experiences shared by patients underscore the growing demand and trust in GIMOTI."

"In the first quarter of 2024, our net revenue of approximately \$1.7 million faced marginal impacts from transient challenges, including a cyberattack on the largest U.S. medical claims processor and an increase in co-pay expenses covered by Evoke. The increase in co-pay expenses was partly due to lower payor reimbursements against higher patient deductibles typical at the year's start. The cyberattack in late February also disrupted new patient enrollments and refill adjudications for GIMOTI. Despite these obstacles, our adaptive strategies and resilience are yielding positive results. Notably, we've achieved a 70% quarter-over-quarter growth in prescriber numbers and a 10% increase in medication fills. Additionally, our strengthened partnership with ASPN Pharmacies is poised to further enhance our service delivery and patient reach. We are confident that the issues from this quarter will fully resolve as the year progresses. Coupled with our strong performance on key sales indicators, we anticipate accelerated growth throughout the remainder of 2024," Mr. D’Onofrio continued.

First Quarter 2024 Developments and Recent Highlights:

- **Maximizing GIMOTI Awareness Building Efforts through KOLs & Conferences**
 - Held virtual webinar featuring Michael Cline, DO., Medical Director Gastroparesis Clinic at the Cleveland Clinic in April to discuss compelling healthcare resource utilization data showing improved hospitalization rates, and his view on patient experience with GIMOTI.
 - Abstract focused on the healthcare resource utilization data of diabetic gastroparesis care in women using nasal metoclopramide to be presented at Digestive Disease Week ("DDW") 2024 in Washington D.C.
 - Transitioned Pharmacy Service Partnership & Initiated First Year of Distribution with ASPN Pharmacies
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- Scaling up GIMOTI distribution infrastructure and improving patient outcomes with access to ASPN’s expansive pharmacy network. Initiated pharmacy service agreement with ASPN in November 2023.
- **Improved Cash Position**
- In Q1, the Company raised \$8.8M in gross proceeds from a public offering and subsequent exercise of warrants with fundamental, healthcare-oriented institutional investors providing the company runway into the fourth quarter of 2024 with up to an additional \$21.8M available if common stock warrants are exercised in full.

"During our recent Key Opinion Leader (KOL) webinar, Dr. Michael Cline from the Cleveland Clinic discussed the limitations of oral metoclopramide for treating gastroparesis, noting its unpredictable effects due to gastric emptying variations. GIMOTI addresses these issues with its nasal delivery system, bypassing the faulty GI track in these patients. Moving forward, we will amplify our promotional efforts for GIMOTI through the insights of our KOLs, real-world data, and conferences such as the upcoming Digestive Disease Week (DDW). Later this month at DDW we will present data on the clinical use of nasal metoclopramide in women with gastroparesis, highlighting its benefits and practical application," Mr. D’Onofrio concluded.

Fourth Quarter and Full Year 2023 Financial Review and Outlook

For the first quarter of 2024, net product sales were approximately \$1.7 million compared with \$0.8 million during the first quarter of 2023, and the net loss was approximately \$1.6 million, or \$0.17 per share compared with \$2.2 million, or \$0.67 per share, for the first quarter of 2023.

For the first quarter of 2024, selling, general and administrative expenses were approximately \$3.1 million compared to \$2.8 million for the first quarter of 2023. 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 \$3.2 million compared to \$3.0 million for the same period in 2023.

As of March 31, 2024, cash and cash equivalents were approximately \$9.7M which includes the funds recently raised from our public offering and related warrant exercises. 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 first quarter of 2025.

Evoke reiterates its net revenue guidance in 2024 of approximately \$14 million. Evoke’s 2024 guidance is dependent on its current business and expectations, including recent growth rates in net sales, assumptions regarding reimbursements and prescription fills, as well as factors that are outside of our control, such as the global macroeconomic and geopolitical environment, continued supply chain constraints and inflationary pressures.

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.

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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 (≥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: guidance regarding 2024 net product sales; potential future prescribing trends for GIMOTI based on Evoke’s or EVERSANA’s marketing efforts; Evoke’s commercialization plans, including the potential that GIMOTI could become the standard of care for gastroparesis; the potential for additional funds from the exercise of outstanding warrants and Evoke’s expected cash runway. 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 may not be able to achieve its guidance for 2024 including as a result of decreased demand for GIMOTI; 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; Evoke may use its capital resources sooner than expected; warrant holders may choose not to exercise any of the outstanding warrants; 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:

Daniel Kontoh-Boateng
DKB Partners
Tel: 862-213-1398
dboateng@dkbpartners.net

Evoke Pharma, Inc
Condensed Balance Sheets

	March 31, 2024	December 31, 2023
	(unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 9,702,755	\$ 4,739,426
Accounts receivable, net of allowance for credit losses of \$0	1,451,904	673,071
Prepaid expenses	704,215	885,040
Inventories	588,776	481,840
Other current assets	6,312	47,532
Total current assets	12,453,962	6,826,909
Deferred offering costs	-	241,637
Total assets	\$ 12,453,962	\$ 7,068,546
Liabilities and stockholders' equity (deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,953,959	\$ 1,711,778
Accrued compensation	265,881	1,324,010
Note Payable	5,000,000	5,000,000
Accrued interest payable	1,736,953	1,612,295
Total current liabilities	8,956,793	9,648,083
Total liabilities	8,956,793	9,648,083
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value; authorized shares - 50,000,000; issued and outstanding shares 8,597,405 and 3,343,070 at March 31, 2024 and December 31, 2023, respectively	859	334
Additional paid-in capital	128,515,568	120,859,567
Accumulated deficit	(125,019,258)	(123,439,438)
Total stockholders' equity (deficit)	3,497,169	(2,579,537)
Total liabilities and stockholders' equity (deficit)	\$ 12,453,962	\$ 7,068,546

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

	Three Months Ended March 31,	
	2024	2023
Net product sales	\$ 1,735,490	\$ 810,408
Operating expenses:		
Cost of goods sold	92,529	50,591
Research and development	4,645	66,990
Selling, general and administrative	3,139,536	2,847,940
Total operating expenses	3,236,710	2,965,521
Loss from operations	(1,501,220)	(2,155,113)
Other income (expense):		
Interest income	46,058	35,331
Interest expense	(124,658)	(123,288)
Total other expense	(78,600)	(87,957)
Net loss	\$ (1,579,820)	\$ (2,243,070)
Net loss per share of common stock, basic and diluted	\$ (0.17)	\$ (0.67)
Weighted-average shares used to compute basic and diluted net loss per share	9,082,139	3,343,070
