

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): March 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 March 14, 2024, Evoke Pharma, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 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	<a href="#">Press Release issued on March 14, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: March 14, 2024

By: /s/ Matthew J. D'Onofrio

Name: Matthew J. D'Onofrio

Title: President, Chief Operating Officer and Secretary

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## **Evoke Pharma Reports Fourth Quarter and Full Year 2023 Financial Results**

*Fiscal year 2023 net product sales from prescriptions totaled approximately \$5.2M, a 107% increase from 2022*

*Company projects \$14M in net revenue for 2024*

SOLANA BEACH, Calif., March 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<sup>®</sup> (metoclopramide) nasal spray, today announced its financial results for the fourth quarter and full year ended December 31, 2023, and recent corporate developments.

"In 2023, we focused on operational excellence to expand GIMOTI's market share and ensure its availability for patients requiring an improved gastroparesis treatment. Our commercial team's dedicated efforts yielded a 107% increase in year-over-year revenue," stated Dave Gonyer, R.Ph., CEO of Evoke Pharma. "The new Healthcare Resource Utilization (HCRU) data has only been available to our commercial team since near the end of the year. We believe it is just starting to drive growth beginning with the addition of new prescribers, a rise in prescription fills, and an uptick in patient enrollments, solidifying 2023 as an important year for our product's market presence. As of December 31, 2023, we've seen a 66% rise in cumulative prescribers from the previous year, totaling 1,689. Prescription fills and patient enrollments also climbed significantly by 100% and 88% respectively, year-over-year," Mr. Gonyer added.

### **Fourth Quarter and Full Year 2023 Developments and Recent Highlights:**

- **Continued Advocacy for GIMOTI as the Standard of Care for Diabetic Gastroparesis Treatment**

- Healthcare resource utilization data presented at DDW 2023 revealed that there is statistically significantly less burden on healthcare resources and facilities such as hospital admissions, emergency department and physician office visits with patients who are being prescribed GIMOTI versus those on oral metoclopramide.

- Based on the reduced utilization data, additional compelling cost data presented in a distinguished plenary session at ACG 2023 demonstrated financial savings benefits of GIMOTI for patients and payors compared to oral metoclopramide.

- Abstract focused on the HCRU of diabetic gastroparesis care in women using nasal metoclopramide to be presented at DDW 2024.

- **Transitioned Pharmacy Service Partnership to ASPN Pharmacies**

- Aiming to enhance patient prescription process and enhance revenues through ASPN's extensive network of partners with broader PBM agreements.

- **Fortified Patent Estate for GIMOTI**

- Two patents issued in 2023 covering the methods of use for GIMOTI including two Orange Book listings.

- Teva Pharmaceuticals determination not to pursue a paragraph 4 certification against GIMOTI without financial or other consideration further enhanced Evoke's intellectual property position and eliminated 180-day exclusivity opportunity for later possible generic seeking entities for the future.

- **Improved Cash Position**

- In February 2024, the Company closed a \$7.5M public offering with fundamental, healthcare-oriented institutional

investors providing the company runway into the fourth quarter of 2024 with up to an additional \$22.5M available if common stock warrants are exercised in full.

Mr. Gonyer concluded, "2023 was a milestone year for GIMOTI with new real-world evidence demonstrating its superiority over traditional treatments and data showing a marked decrease in hospitalization and ER visits for GIMOTI over oral metoclopramide which translated into savings of over \$15,000 per patient in only six months". Our results at major gastroenterology conferences including Digestive Disease Week 2023 have strengthened market trust in GIMOTI, bolstering our goal to make it the standard treatment for diabetic gastroparesis. Current and new IP protections, coupled with new inquiries about the prevalence GLP-1 associated diabetic gastroparesis, and the recent capital boost from our public offering further position us to scale our operations and achieve sustained business growth."

#### **Fourth Quarter and Full Year 2023 Financial Review and Outlook**

For the fourth quarter of 2023, net product sales were approximately \$1.7 million compared with \$0.8 million during the fourth quarter of 2022, and the net loss was approximately \$2.0 million, or \$0.59 per share compared with \$1.8 million, or \$0.54 per share, for the fourth quarter of 2022. For the year ended December 31, 2023, net product sales were approximately \$5.2 million compared with approximately \$2.5 million for the year ended December 31, 2022, and the net loss was approximately \$7.8 million, or \$2.33 per share, compared with a net loss of \$8.2 million, or \$2.62 per share, for the year ended December 31, 2022. The year-over-year increase in revenue was due to higher net product sales in 2023, resulting from:

- Prescription sales through pharmacy service partnership with ASPN Pharmacy;
- Recapture of prescriptions sent to retail pharmacies without ability to order product; and
- Marketing of head-to-head real-world data comparing Gimoti to oral metoclopramide showing improvements in fewer hospitalizations and ER visits with GIMOTI.

Research and development expenses totaled approximately \$23,000 for the fourth quarter of 2023 compared with \$27,000 for the fourth quarter of 2022. For the full year of 2023, research and development expenses were approximately \$0.2 million compared with approximately \$0.3 million for the prior year.

For the fourth quarter of 2023 selling, general and administrative (SG&A) expenses were approximately \$3.5 million compared with \$2.3 million for the fourth quarter of 2022. For the year ended December 31, 2023, selling, general and administrative expenses were approximately \$12.2 million versus approximately \$9.6 million for the year ended December 31, 2022. The increase in SG&A costs year-over-year resulted primarily from higher marketing and Eversana profit sharing costs. We expect that selling, general and administrative expenses will increase in the future as we continue to progress with the commercialization of GIMOTI.

Total operating expenses for the fourth quarter of 2023 were approximately \$3.6 million compared with \$2.3 million for the same period of 2022. For the year ended December 31, 2023, total operating expenses were approximately \$12.6 million compared with approximately \$10.3 million for the full year of 2022.

As of December 31, 2023, cash and cash equivalents were approximately \$4.7 million. We believe, based on our current operating plan, that our existing cash and cash equivalents, including the proceeds of approximately \$6.1 million from the public offering closed in February 2024, as well as future cash flows from net product sales of Gimoti, will be sufficient to fund our operations into the fourth quarter of 2024.

Evoke projects net revenue 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](http://www.EvokePharma.com) for more information.  
Follow GIMOTI on Facebook  
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 the FDA. Visit [www.fda.gov/medwatch](http://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

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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:**

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*Financial Statements to Follow*

Evoke Pharma, Inc.  
Balance Sheet

	December 31,	
	2023	2022
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 4,739,426	\$ 9,843,699
Accounts receivable	673,071	624,832
Prepaid expenses	885,040	952,954
Inventory	481,840	289,378
Other current assets	47,532	11,551
Total current assets	6,826,909	11,722,414
Deferred offering costs	241,637	-
Operating lease right-of-use asset	-	129,074
Total assets	\$ 7,068,546	\$ 11,851,488
<b>Liabilities and stockholders' equity (deficit)</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,711,778	\$ 934,312
Accrued compensation	1,324,010	591,158
Operating lease liability	-	129,074
Total current liabilities	3,035,788	1,654,544
Long-term Liabilities:		
Note payable	5,000,000	5,000,000
Accrued interest payable	1,612,295	1,112,295
Total long-term liabilities	6,612,295	6,112,295
Total liabilities	9,648,083	7,766,839
<b>Commitments and contingencies (Note 3)</b>		
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; authorized shares — 5,000,000 at December 31, 2023 and 2023; issued and outstanding shares — 0 at December 31, 2023 and 2022 respectively	-	-
Common stock, \$0.0001 par value; authorized shares — 50,000,000 at December 31, 2023 and 2022; issued and outstanding shares — 3,343,070 at December 31, 2023 and 2022, respectively	334	334
Additional paid-in capital	120,859,567	119,731,458
Accumulated deficit	(123,439,438)	(115,647,143)
Total stockholders' equity (deficit)	(2,579,537)	4,084,649
Total liabilities and stockholders' equity (deficit)	\$ 7,068,546	\$ 11,851,488



Evoke Pharma, Inc.  
Statement of Operations

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Net product sales	\$ 5,180,630	\$ 2,508,645
Operating expenses:		
Cost of goods sold	201,879	370,394
Research and development	181,907	300,789
Selling, general and administrative	12,227,735	9,623,599
Total operating expenses	12,611,521	10,294,782
Loss from operations	(7,430,891)	(7,786,137)
Other income (expense):		
Interest income	138,596	62,007
Interest expense	(500,000)	(500,000)
Total other income (expense)	(361,404)	(437,993)
Net loss	\$ (7,792,295)	\$ (8,224,130)
Net loss per share of common stock, basic and diluted	\$ (2.33)	\$ (2.62)
Weighted-average shares used to compute basic and diluted net loss per share	3,343,070	3,143,626

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