

**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 21, 2023

Evoked 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 March 21, 2023, Evoke Pharma, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 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 March 21, 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: March 21, 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 Fourth Quarter and Full Year 2022 Financial Results

Fiscal year 2022 net product sales from prescriptions increased by 179% to \$2.5 million versus 2021

Patient enrollment increased by 149% compared with 2021

SOLANA BEACH, Calif., March 21, 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 fourth quarter and full year ended December 31, 2022, and recent corporate developments.

"Evoke's fiscal year 2022 was a period of tremendous growth and progress on several key fronts. Year-over-year revenues, new prescribers, prescription fills, and patient enrollments showed significant improvement in 2022 compared with 2021. In 2021, our prime achievement was to call attention to GIMOTI's value proposition in the marketplace. In 2022, we continued to increase patient and physician awareness and to make progress toward our objective of having GIMOTI become the standard of care for treating diabetic gastroparesis," said David A. Gonyer, R.Ph., Evoke Pharma's CEO.

"In the fourth quarter of 2022, our net product sales from prescriptions decreased slightly to \$796,000, from \$832,000 in the third quarter of 2022, resulting from increased prescription sales to uninsured or under-insured patients. Prescription fills increased 8% in the fourth quarter 2022 compared to the third quarter while full year prescription fills increased 178%. In addition, the number of cumulative GIMOTI prescribers increased by approximately 25%, to 1,017 healthcare providers (HCPs) as of December 31, 2022, from 812 through September 30, 2022," concluded Mr. Gonyer.

Fourth Quarter and Full Year 2022 Developments and Recent Highlights:

- **Increased clinical and commercial validation of GIMOTI as a critically needed non-oral drug delivery for gastroparesis**
 - Company's abstract selected for plenary lecture presentation at Digestive Disease Week (DDW) taking place May 6-9, 2023 to provide healthcare resource utilization data on the effectiveness of GIMOTI as a potential "needle-moving" solution in the treatment of gastroparesis.
 - Abstract to be presented at March 21-24, 2023 Academy of Managed Care Pharmacy (AMCP) annual meeting will offer real-world analysis of patients in improving their symptoms and reducing their need to visit the ER or take more invasive steps to treat their condition.
- **Notably bolstered patent portfolio and successfully settled Teva suit**
 - Favorable outcome enhances company's intellectual property in important category of healthcare innovation.
 - Company gained additional traction with U.S. Patent & Trademark Office (USPTO) patent allowances to ensure the availability of GIMOTI among patients and health care providers in the U.S.
- **Inked channel sales partnerships in conjunction with Eversana to improve GIMOTI Market Access**
 - Integrated Vitacare, an e-prescription tool to help patients understand coverage and identify available savings opportunities and facilitates communications between providers and payors.
 - Added direct-to-consumer telehealth platform for GIMOTI through collaboration with UpScriptHealth.
- **Presented distinct tardive dyskinesia real-world data analyses at DDW 2022**
 - Selected as a poster of distinction, last year at DDW, Evoke presented data that demonstrated a lower risk of tardive dyskinesia (TD) associated with metoclopramide usage compared to previous reports.

- Supports safety profile of only approved molecule in U.S. to treat symptoms of acute and recurrent diabetic gastroparesis.
- **Growing Product Recognition and Market Acceptance**
 - GIMOTI nominated for 2022 Healo Industry Breakthrough Award amongst other novel gastroenterology products from major pharmaceutical companies.
 - Patient and healthcare provider surveys conducted by Eversana showed that the product is incrementally beneficial and more effective for patients and prescribers.
- **Covered additional state Medicaid territories**
 - Received Medicaid approvals in Texas, Florida, and New York improving market access for millions of lives within those networks.

Fourth Quarter and Full Year 2022 Financial Review

For the fourth quarter of 2022, net product sales were approximately \$796,000 compared with \$361,000 during the fourth quarter of 2021, and the net loss was approximately \$1.8 million, or \$0.54 cents per share compared with \$1.7 million, or \$0.61 per share, for the fourth quarter of 2021. For the year ended December 31, 2022, net product sales were approximately \$2.5 million compared with approximately \$1.6 million for the year ended December 31, 2021, and the net loss was approximately \$8.2 million, or \$2.62 per share, compared with a net loss of \$8.5 million, or \$3.18 per share, for the year ended December 31, 2021. (The annual net losses per share reflect the company's June 2022 1-for-12 reverse stock split.) The year-over-year increase in revenue was due to higher net product sales in 2022, resulting from:

- increased face-to-face interaction with physicians (primarily gastroenterologists) and other healthcare providers by our sales partner, Eversana;
- greater number of physicians within larger gastroenterology teams prescribing GIMOTI after first-physician adoption; and
- prescription sales through our vitaCare (e-prescription service).

Research and development expenses totaled approximately \$27,000 for the fourth quarter of 2022 compared with \$36,000 for the fourth quarter of 2021. For the full year of 2022, research and development expenses were approximately \$0.3 million compared with approximately \$0.6 million for the prior year. Since receiving FDA approval of GIMOTI in June 2020, Evoke's research and development costs continued to decrease and shift to commercialization and selling costs.

For the fourth quarter of 2022 selling, general and administrative (SG&A) expenses were approximately \$2.3 million compared with \$1.7 million for the fourth quarter of 2021. For the year ended December 31, 2022, selling, general and administrative expenses were approximately \$9.6 million versus approximately \$8.9 million for the year ended December 31, 2021. 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 2022 were approximately \$2.3 million compared with \$1.8 million for the same period of 2021. For the year ended December 31, 2022, total operating expenses were approximately \$10.3 million compared with approximately \$9.8 million for the full year of 2021.

As of December 31, 2022, cash and cash equivalents were approximately \$9.8 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 third 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/search/top?q=gimoti%C2%AE%20\(metoclopramide\)%20nasal%20spray](https://www.facebook.com/search/top?q=gimoti%C2%AE%20(metoclopramide)%20nasal%20spray)

Follow Evoke Pharma on Facebook: <https://www.facebook.com/Evoke-Pharma-Inc-131313647029724>

Follow Evoke Pharma on LinkedIn: <https://www.linkedin.com/company/evokepharma/>

About EVERSANA

EVERSANA™ is a leading provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product lifecycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science solutions for a healthier world. To learn more about EVERSANA, visit www.eversana.com or connect through LinkedIn and 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: 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. 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.
Balance Sheet

	December 31,	
	2022	2021
Assets		
Current Assets:		
Cash and cash equivalents	\$ 9,843,699	\$ 9,144,710
Accounts receivable, net	624,832	295,193
Prepaid expenses	952,954	923,746
Inventory, net	289,378	185,534
Other current assets	11,551	11,551
Total current assets	11,722,414	10,560,734
Operating lease right-of-use asset	129,074	12,428
Total assets	\$ 11,851,488	\$ 10,573,162
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 934,312	\$ 874,028
Accrued compensation	591,158	519,317
Operating lease liability	129,074	12,428
Total current liabilities	1,654,544	1,405,773
Long-term Liabilities:		
Note payable	5,000,000	5,000,000
Accrued interest payable	1,112,295	612,295
Total long-term liabilities	6,112,295	5,612,295
Total liabilities	7,766,839	7,018,068
Stockholders' equity:		
Preferred stock, \$0.0001 par value; authorized shares — 5,000,000 at December 31, 2022 and 2021; issued and outstanding shares — 0 at December 31, 2022 and 2021 respectively	-	-
Common stock, \$0.0001 par value; authorized shares — 50,000,000 at December 31, 2022 and 2021; issued and outstanding shares — 3,343,070 and 2,721,373 at December 31, 2022 and 2021, respectively	334	272
Additional paid-in capital	119,731,458	110,977,835
Accumulated deficit	(115,647,143)	(107,423,013)
Total stockholders' equity	4,084,649	3,555,094
Total liabilities and stockholders' equity	\$ 11,851,488	\$ 10,573,162

Evoke Pharma, Inc.
Statement of Operations

	Year Ended December 31,	
	2022	2021
Net product sales	\$ 2,508,645	\$ 1,618,076
Operating expenses:		
Cost of goods sold	370,394	328,118
Research and development	300,789	590,476
Selling, general and administrative	9,623,599	8,851,129
Total operating expenses	10,294,782	9,769,723
Loss from operations	(7,786,137)	(8,151,647)
Other income (expense):		
Forgiveness of paycheck protection loan and accrued interest	-	105,130
Interest income	62,007	8,615
Interest expense	(500,000)	(500,050)
Total other income (expense)	(437,993)	(386,305)
Net loss	\$ (8,224,130)	\$ (8,537,952)
Net loss per share of common stock, basic and diluted	\$ (2.62)	\$ (3.18)
Weighted-average shares used to compute basic and diluted net loss per share	3,143,626	2,682,145

