

**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): November 09, 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)

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 November 9, 2022, Evoke Pharma, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 November 9, 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: November 09, 2022

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



Exhibit 99.1

Evoked Pharma Reports Record Third Quarter 2022 Financial Results

80% increase in GIMOTI® net revenue over Q2 2022
56% increase of GIMOTI prescription fills in Q3 compared to Q2
13% increase of new prescribers of GIMOTI over Q2

SOLANA BEACH, Calif., November 9, 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 third quarter ended September 30, 2022 and recent corporate developments.

“Evoke delivered record financial and operating results based on the key metrics we use to gauge the overall strength and value of our business,” said David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. “Net product sales of GIMOTI during the third quarter of 2022 grew 80% to approximately \$832,000 compared to the second quarter of 2022. Evoke also recorded an increase of 56% in GIMOTI prescriptions dispensed in Q3 compared to Q2.”

“During the third quarter, we completed the transition of our reimbursement program to vitaCare, a wholly owned subsidiary of GoodRx. Inbound prescriptions during Q3 increased 32% over Q2 2022. In addition, the number of GIMOTI prescribers increased to a record 143, which represents a 13% increase over Q2. GIMOTI had 812 cumulative new prescribers as of September 30, an increase of 21% over Q2 2022. As we approach 2023, we are highly encouraged and motivated by our metrics in all categories and we look forward to continuing our mission to improve the quality of life for patients suffering from diabetic gastroparesis,” Mr. Gonyer concluded.

Third Quarter 2022 Developments and Recent Progress:

Company received Notice of Allowance from USPTO for a patent related to GIMOTI

- Entitled “Treatment of Moderate and Severe Gastroparesis,” the patent expires in 2037, and protects Phase 3 clinical trial outcomes data that shows efficacy with nasal metoclopramide formulations for persons suffering from moderate-to-severe diabetic gastroparesis.

• New Patient Experience Survey Reported Positive Findings for GIMOTI

- Survey conducted with 201 gastroparesis patients.
 - Patients reported the greatest symptom improvement and ease of use with Gimoti compared to competing products (i.e., oral or liquid forms of metoclopramide, and Domperidone).
 - Similar or better side effect profile compared to competing products.
 - Similar to clinical trial findings for specific symptom improvement, patients reported the highest nausea relief and abdominal pain relief with Gimoti compared to competing products.
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- **Launched a telehealth solution for patients with UpScriptHealth partnership**
 - Allows patients without regular access to care due to their remote location, lack of transportation, affordability, or work schedule to receive care via a telehealth option.
 - Makes consultations rapidly available and allows for treatment initiation within just a few days, if medically appropriate.
- **GIMOTI nominated as a finalist for Healio Disruptive Innovator of the Year Award**
 - GIMOTI selected among other novel gastroenterology products from six major pharmaceutical companies.
 - Nomination at the 2022 American College of Gastroenterology Scientific Meeting further highlights the novelty of a disruptive non-oral treatment for a disease where traditional oral treatments are noted to be unreliable.

Third Quarter 2022 Financial Review

For the third quarter of 2022, net sales were approximately \$832,000 compared with approximately \$462,000 in the second quarter of 2022, an increase of approximately 80%. Net sales for the third quarter of 2021 were approximately \$247,000, which excludes approximately \$683,000 sold to a third party for research purposes. The increase in net sales sequentially and year over year was due to higher number of GIMOTI prescriptions. Net loss was approximately \$2.0 million or \$0.60 per share in the third quarter of 2022, compared with approximately \$2.2 million or \$0.71 per share in the second quarter of 2022. Net loss for the third quarter of 2021 was approximately \$2.0 million or \$0.73 per share. Research and development (R&D) expenses for the three months ended September 30, 2022 were approximately \$40,000 compared with approximately \$191,000 for the three months ended June 30 2022 and approximately \$82,000 for the third quarter of 2021. R&D expenses in the second quarter of 2022 were higher as a result of increased, non-recurring manufacturing testing.

For the third quarter of 2022, selling, general and administrative (SG&A) expenses were approximately \$2.6 million compared with \$2.3 million for the second quarter of 2022. SG&A expenses were essentially unchanged from the third quarter of 2021. Total operating expenses for the third quarter of 2022 were approximately \$2.7 million compared with \$2.6 million for the second quarter of 2022 and approximately \$2.8 million for the third quarter of 2021.

As of September 30, 2022, the company's cash and cash equivalents were approximately \$12.4 million. Based on the company's current operating plan, it believes that existing cash and cash equivalents as well as anticipated future cash flows from net product sales of GIMOTI will be sufficient to fund operations into the second quarter of 2023.

Conference Call Information

Management will host a conference call on Wednesday, November 9, 2022, at 4:30 p.m. ET to discuss the results. The dial-in numbers for the conference call are **(800) 245-3047 and (203) 518-9765 for international callers. The conference ID number is EVOKQ322.**

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-](https://www.facebook.com/GIMOTI-metoclopramide-nasal-spray-104672345100289)

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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 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: the potential of GIMOTI to improve the quality of life for patients suffering from diabetic gastroparesis; potential future prescribing trends for GIMOTI; the anticipated scope and term of any patent protection for 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 maintain its existing commercial services agreement with EVERSANA or, if it is terminated or Evoke otherwise elects to do so, retain an alternative organization, or develop its own sales and marketing capability, to commercialize and distribute 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.

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