# 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 07, 2024**

# EVOKE PHARMA, INC.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-36075** | **20-8447886** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |
| **420 Stevens Avenue, Suite 230<br>Solana Beach, California** | | **92075** |
| **(Address of Principal Executive Offices)** | | **(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 7, 2024, Evoke Pharma, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 November 7, 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: November 7, 2024

By: /s/ Matthew J. D'Onofrio

Name: Matthew J. D'Onofrio
Title: Chief Executive Officer

**Evoke Pharma, Inc. Reports Third Quarter 2024 Financial Results**

*GIMOTI third quarter net product sales of $2.7 million, highest quarterly revenue ever with a 70% increase year-over-year*

*Strong cumulative prescriber growth, 45% year-over-year increase*
*52% year-over-year prescription fill increase; 39% increase since Q1 2024*

*Real-world data presented at ACG 2024 demonstrates that GIMOTI significantly enhanced outcomes for patients on GLP-1 therapy, marking it as a promising supportive care option compared to oral metoclopramide.*

SOLANA BEACH, Calif., November 7, 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 third quarter ended September 30, 2024, and recent corporate developments.

“We are encouraged by the strong year-over-year growth metrics we continue to see for GIMOTI, including a 70% year-over-year increase in net product sales and significant gains in prescriber and prescription fill rates. We continue to grow revenue with this being the highest quarter of revenue on record” said Matt D’Onofrio, CEO of Evoke Pharma. “The strong response to GIMOTI among healthcare providers and patients underscores its growing value as an innovative non-oral treatment option for diabetic gastroparesis. With award-winning real-world data presented at ACG 2024, GIMOTI has demonstrated its potential to treat diabetic gastroparesis even with those undergoing GLP-1 therapy.”

“The recent data presented at ACG 2024 highlights GIMOTI’s ability to significantly reduce healthcare visits, including hospitalizations, underscoring the need for better alternatives to traditional oral treatments. Coupled with our strategic initiatives to expand access and engage more prescribers, we are well-positioned to increase GIMOTI’s reach and help more patients find meaningful relief. The positive feedback from both patients and providers strengthens our resolve to reshape the care paradigm and ensure that people with gastroparesis have access to an effective and innovative option like GIMOTI,” said Chris Quesenberry, Chief Commercial Officer of GIMOTI.

“Our dedicated mission is to challenge the notion that gastroparesis 'patients are doing fine' with current treatment options, as we know firsthand that many individuals with diabetic gastroparesis continue to struggle despite existing therapies. According to a survey from IFFGD (gastroenterology patient support organization), 65% of patients with Diabetic Gastroparesis are dissatisfied with current therapies. Based on these data and the efficacy of GIMOTI, we believe patients may benefit by switching from oral to nasally-administered GIMOTI. It is directly absorbed into the bloodstream and does not rely on a dysfunctional stomach to work. In GIMOTI,

providers have an alternative to help patients they did not previously think they could help as well as an option to re-challenge patients who did not have optimal efficacy using oral medications.” Chris added.

**Third Quarter 2024 and Year-to-Date Developments and Recent Highlights:**

- **Continued Commercial Progress with GIMOTI**
  - Strengthened patient access and streamlined prescription processing with the addition of multiple pharmacy partners, expanding GIMOTI’s reimbursement coverage and availability across key geographic areas.
  - Improved insurance reimbursement rates, reducing patient reliance on savings programs due to increased prescription coverage; Medicare and Medicaid programs accounted for approximately 34% of filled GIMOTI prescriptions in the first nine months of 2024, supporting accessibility for a broader patient demographic.

- **Compelling Data Unveiled at American College of Gastroenterology 2024 Meeting in October**
  - Presented posters with data showing statistically significant improvement in patient outcomes for GLP-1 users with diabetic gastroparesis while taking GIMOTI.
  - Poster won the Presidential Poster Award as one of the top 5% of data accepted by the conference and also selected as the Outstanding Research Award in the Stomach Category.

- **Robust Balance Sheet with Extended Runway**
  - As of September 30, the Company had cash and cash equivalents of approximately $11.3 million which includes approximately $10.8 million from warrant exercise financing activities through 3Q 2024.
  - In October 2024, the Company also raised approximately $3.5 million through the exercise of warrants by existing investors.
  - The Company anticipates its current cash on hand will fund its operations into the fourth quarter of 2025.
- **Board of Directors Expansion**
  - In October 2024, the Company announced the appointment of Ben Smeal to its Board of Directors fulfilling a condition set by Evoke’s existing investor, Nantahala Capital Management in connection with the warrant financing that occurred in September.

**Third Quarter 2024 Financial Review and Outlook**

For the third quarter of 2024, net product sales were approximately $2.7 million compared to $1.6 million during the third quarter of 2023, and the net loss was approximately $1.3 million, or $0.94 per share compared with $1.7 million, or $6.08 per share, for the third quarter of 2023.

For the third quarter of 2024, selling, general and administrative expenses were approximately $3.8 million compared to $3.1 million for the third quarter of 2023. The $0.7 million increase was due to higher professional fees and reimbursement for expanded marketing efforts and profit-sharing activity with EVERSANA.

Total operating expenses for the third quarter of 2024 were approximately $3.9 million compared to $3.2 million for the same period in 2023.

Based on net sales generated in the first three quarters of 2024, Evoke is revising its 2024 guidance to $9.5-10.0 million from a range of $11- 12 million, still reflecting almost a doubling from the previous year, if achieved. 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.
Follow GIMOTI 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, effectson 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**

| | September 30, 2024 (unaudited) | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 11,339,032 | $ 4,739,426 |
| Accounts receivable, net of allowance for credit losses of $0 | 2,022,518 | 673,071 |
| Prepaid expenses | 146,704 | 885,040 |
| Inventories | 493,408 | 481,840 |
| Other current assets | 36,421 | 47,532 |
| Total current assets | 14,038,083 | 6,826,909 |
| Deferred offering costs | 115,488 | 241,637 |
| Total assets | $ 14,153,571 | $ 7,068,546 |
| **Liabilities and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 2,188,164 | $ 1,711,778 |
| Accrued compensation | 590,634 | 1,324,010 |
| Note payable | 5,000,000 | 5,000,000 |
| Accrued interest payable | 1,987,637 | 1,612,295 |
| Total current liabilities | 9,766,435 | 9,648,083 |
| Total liabilities | 9,766,435 | 9,648,083 |
| Commitments and contingencies | | |
| Stockholders' equity (deficit): | | |
| Preferred stock, $0.0001 par value; authorized shares — 5,000,000 as of September 30, 2024 and December 31, 2023; issued and outstanding shares — zero as of September 30, 2024 and December 31, 2023 | — | — |
| Common stock, $0.0001 par value; authorized shares — 100,000,000 and 50,000,000 as of September 30, 2024 and December 31, 2023, respectively; issued and outstanding shares — 894,843 and 278,558 as of September 30, 2024 and December 31, 2023, respectively | 89 | 28 |
| Additional paid-in capital | 131,985,913 | 120,859,873 |
| Accumulated deficit | (127,598,866) | (123,439,438) |
| Total stockholders' equity (deficit) | 4,387,136 | (2,579,537) |
| Total liabilities and stockholders' equity (deficit) | $ 14,153,571 | $ 7,068,546 |

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

| | Three Months Ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Net product sales | $ 2,654,186 | $ 1,562,860 |
| Operating expenses: | | |
| Cost of goods sold | 104,024 | 34,908 |
| Research and development | 11,677 | — |
| Selling, general and administrative | 3,824,142 | 3,131,389 |
| Total operating expenses | 3,939,843 | 3,166,297 |
| Loss from operations | (1,285,657) | (1,603,437) |
| Other income (expense): | | |
| Interest income | 99,294 | 35,558 |
| Interest expense | (126,027) | (126,028) |
| Total other expense | (26,733) | (90,470) |
| Net loss | $ (1,312,390) | $ (1,693,907) |
| Net loss per share of common stock, basic and diluted | $ (0.94) | $ (6.08) |
| Weighted-average shares used to compute basic and diluted net loss per share | 1,399,882 | 278,558 |