# 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): October 28, 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. ☐

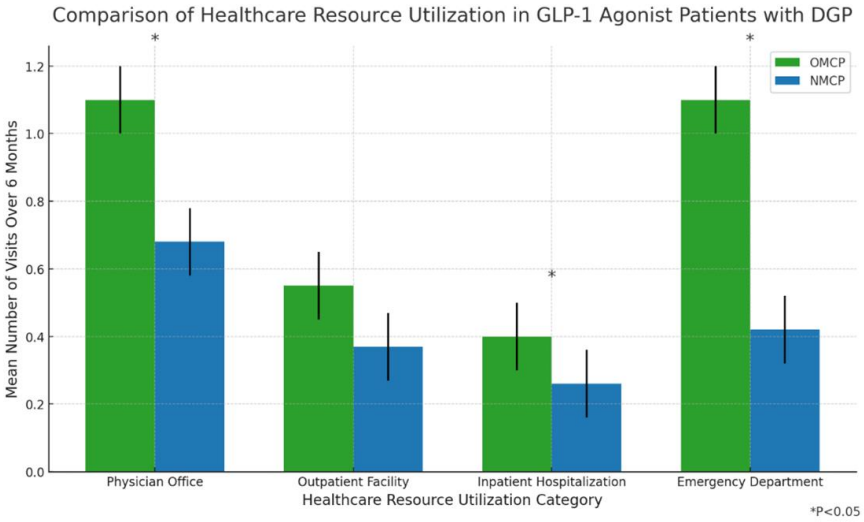
**Item 8.01 Other Events.**

On October 28, 2024, Evoke Pharma, Inc. (the "Company" or "Evoke") announced the presentation of data studying diabetic gastroparesis ("DGP") patients using glucagon-like peptide-1 ("GLP-1") receptor agonists and also using GIMOTI (metoclopramide nasal spray) at the American College of Gastroenterology ("ACG") 2024 Annual Meeting.

The real-world retrospective study evaluated the impact of GIMOTI in patients with DGP who were concurrently using GLP-1 receptor agonists. GLP-1 drugs are commonly prescribed for type 2 diabetes, and with the recent approval of GLP-1/GIP medications, there have been increasing reports of these drugs exacerbating gastrointestinal symptoms, specifically gastroparesis, due to their mechanism of action which delays gastric emptying. The study compared healthcare resource utilization ("HRU") between patients using GIMOTI nasal metoclopramide ("NMCP") and those on oral metoclopramide ("OMCP"), specifically focusing on individuals with a prior GLP-1 prescription. Adult patients with a DGP diagnosis and at least 6 months of data pre- and post-index (treatment initiation), continuous data were included. Significant reductions in both all-cause and gastroparesis-related office and emergency room visits were observed in patients treated with GIMOTI versus oral metoclopramide.

**Key Study Findings Presented at ACG 2024:**

- Patients with prior GLP-1 history had reduced HRU after taking NMCP.
  - In NMCP patients, all-cause emergency department (ED) visits decreased by 55% (mean [SD]: 0.25 [1.13] post-index vs. 0.55 [1.30] pre-index; P=0.063); and
  - DGP- related ED visits decreased by 28% (mean [SD]: 0.18 [0.99] post-index vs 0.25 [1.28] pre-index; P=0.203)
- In patients taking GLP-1, those that took NMCP had fewer healthcare visits compared to those taking OMCP.
  - All-cause and DGP-related ED visits were 91% lower (cIRR: 0.09, 95% CI: 0.01, 0.42; P=0.001) and 89% lower (cIRR: 0.11, 95% CI: 0, 0.93; P=0.046) for NMCP vs. OMCP; and
  - All-cause and DGP-related office visits were 41% lower (cIRR: 0.59, 95% CI: 0.37, 0.94; P=0.027) and 66% lower (cIRR: 0.34, 95% CI: 0.017, 0.65; P=0.001) for NMCP vs.OMCP.
- NMCP can be used to effectively treat patients with gastroparesis taking GLP-1 treatment and avoid costly healthcare visits.
  - All-cause clinic, outpatient, and inpatient visits showed similar trends favoring NMCP vs. OMCP.
  - In DGP patients with a prior claim for GLP-1, NMCP use was associated with numerically and significantly reduced all-cause and DGP-related HRU compared to pre-treatment utilization and OMCP-treated controls.



The study's specific cohort consisted of 92 total patients between the nasal metoclopramide (NMCP, N=51) and oral metoclopramide (OMCP, N=41) groups. The NMCP group had a slightly older average age (55.1 years) compared to the OMCP group (53.1 years). A notable portion of the NMCP group (31.4%) had experienced hospitalizations or emergency department visits prior to treatment, compared to 19.5% in the OMCP group.

A separate post-hoc analysis focused on safety data for a female subgroup from a previous Phase 3 study that included 36 women using GLP-1 drugs during the 28-day study. The patients had an average age of 51.4 years, with 67% identifying as Caucasian and 33% as Black. Among these, 13 were treated with GIMOTI and 23 with placebo. The majority (94%) of the participants completed the study, with no serious adverse events reported in either group. This analysis indicated no series safety issues and a trend toward nausea improvement when GLP-1 drugs were used with NMCP.

**Safe Harbor Statement**

Evoke cautions you that statements included in this report 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: GIMOTI’s potential to reduce HRU by diabetic gastroparesis patents taking GLP-1 therapies; the possibility that increased use of GLP-1 agonists could increase the need for treatment of gastroparesis or increase the patient base for GIMOTI; and Evoke’s belief that GIMOTI can improve treatment of gastroparesis in patients taking GLP-1 agonists. 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 report due to the risks and uncertainties inherent in Evoke’s business, including, without limitation: Evoke and EVERSANA may not be able to successfully drive market demand for GIMOTI; the results of market research studies may not predict acceptance by patients, healthcare providers or payors; GLP-1 agonists may not increase the number of patients diagnosed with gastroparesis, which remains speculative; alternative treatments for gastroparesis may be developed or approved and may be shown to be superior to GIMOTI; Evoke’s ability to obtain additional financing as needed to support its operations; Evoke may use its capital resources sooner than expected; Evoke’s ability to maintain compliance with Nasdaq’s stockholder’s equity requirements; 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 the Company’s 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 report 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.

**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: October 28, 2024

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