UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): May 23, 2022

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 370 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.)

Securities registered pursuant to Section 12(b) of the Exchange Act

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	EVOK	The Nasdaq Capital Market

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 (*see* General Instruction A.2. below):

☐ 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))

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 May 23, 2022, Evoke Pharma, Inc. ("Evoke" or the "Company") announced the presentation of the results of a retrospective analysis of United States administrative claims data that examined the association between metoclopramide-induced tardive dyskinesia (TD) and potential risk factors at the annual Digestive Disease Week Meeting (DDW 2022) taking place in San Diego, California from May 21-24, 2022.

The Company's product, GIMOTI, is an FDA-approved novel nasal formulation of metoclopramide that is commercially available and specifically designed to deliver a non-oral dose of metoclopramide for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. Non-oral delivery is an important treatment option as gastroparesis causes oral medications to be unpredictably absorbed and vulnerable to one of the key symptoms of the disease, vomiting.

The approved labeling for Gimoti includes a black box warning regarding the risks of TD, a serious movement disorder that is often irreversible, associated with metoclopramide. Previous publications have suggested a strong causal relationship between metoclopramide and TD and reported varying frequencies of TD with metoclopramide use (from 1% to 15%). These reviews are largely outdated, have small sample sizes and different outcome definitions.

Selected as a poster of distinction during DDW 2022, the presentation titled "Revisiting the Risk of Tardive Dyskinesia with Metoclopramide Use: A Real-World Data Driven Epidemiology Study From 2011-2021" is the largest, most robust examination ever conducted to understand the risk of TD. The retrospective analysis was conducted with administrative claims data representing approximately 35% of the US population using the Truven Health MarketScan® Commercial Database. The data gathered between January 1, 2011 and December 31, 2020, comprised an excess of 300 unique employers, 25 different health plans, and 240 million covered lives studying patients with at least twelve (12) months of enrollment in a health insurance plan. Risk ratios were utilized to gauge the association between TD and renal dysfunction, diagnosis of mental health disorders, dopamine receptor blocking agents (DRBA) use, and diabetes. Results of the study concluded that TD is rare among metoclopramide-treated patients, with an incidence of 33.4 per 100,000, and among metoclopramide-treated gastroparesis patients, it was 98.8 per 100,000. In addition, age and sex appear to be significant risk factors for TD, with the highest TD incidence reported among elderly females. Additional risk factors for TD include renal dysfunction, coadministration of DRBAs, diagnosis of mental health disorders, and diabetes. The incidence of TD was also found to increase with prolonged metoclopramide use, with the greatest risk of TD observed after 24 to 48 months of chronic metoclopramide use.

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 benefits of GIMOTI for patients with diabetic gastroparesis. 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: the data from a retrospective analysis may not be as robust as data from a controlled clinical trial and such data does not otherwise effective the black box warning on the Gimoti label related to TD; 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 any 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; 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.

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.

May 23, 2022

EVOKE PHARMA, INC.

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