

**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): August 10, 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.)**

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

**Title of each class
Common Stock,
par value \$0.0001 per share**

**Trading symbol
EVOK**

**Name of each exchange on which registered
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 2.02 Results of Operations and Financial Condition.

On August 10, 2022, Evoke Pharma, Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 10, 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: August 10, 2022

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



Evoked Pharma Reports Second Quarter 2022 Financial Results

Total new inbound prescriptions over 500 for first time, 24% increase over Q1; New cumulative prescribers up 23%; Net revenue increased by 11%.

SOLANA BEACH, Calif., August 10, 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 second quarter ended June 30, 2022, and recent corporate developments.

“Evoke delivered a solid second quarter based on several key metrics and developments,” David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. “Net product sales during the second quarter of 2022 were approximately \$462,000, up 11% compared with first quarter of 2022. Patient prescriptions had the largest number of quarterly enrollments to date and posted an increase of 24%, compared with the first quarter. In addition, the cumulative number of new GIMOTI® prescribers increased by approximately 23%, through June 30, 2022 compared to March 31, 2022. Although filled prescriptions were up modestly in the second quarter, we believe the increased patient enrollments in our vitaCare Prescription Services and EvokeAssist reimbursement programs during Q2 will convert to higher new prescriptions in the second half of the year. Finally, we substantially bolstered our cash reserves in Q2 and extended our operational runway. We believe the additional capital positions us to sustain and increase GIMOTI sales and to capitalize on future market opportunities and provide more patients with access to our novel GIMOTI treatment option.”

Second Quarter 2022 Developments and Recent Progress:

• GIMOTI received Medicaid approvals in Texas and Florida

- Market access improves with approximately 10 million lives in the Texas and Florida Medicaid patient networks combined.
- Adds to the list of other state Medicaid approvals, including New York, which was announced in the 1st quarter of 2022.

• Evoke improves exclusivity around Gimoti with FDA and patent allowances

- Evoke currently has exclusive marketing rights from the U.S. FDA for three (3) years from the original approval date under the Hatch-Waxman Act to protect GIMOTI from generic drug competition.
- Awarded Canadian patent covering the method of use for GIMOTI in July with an expiry in 2029. The new patent adds to two other U.S. Food and Drug Administration (FDA) Orange Book-listed patents under the same title that expire in 2029 and 2030, respectively.

■ Patient Experience Survey Reported Positive Findings for GIMOTI.

- First patient centric survey conducted by Evoke and Eversana indicates increasing patient awareness, trial, and product usage of GIMOTI.

- Essential findings: 100% of current GIMOTI users report seeing at least some symptom improvement, particularly diminished nausea.
- **Company presented real-world data analyses demonstrating a lower risk of tardive dyskinesia (TD) associated with metoclopramide usage compared to previous reports.**
 - Evoke poster at Digestive Disease Week (DDW) 2022 in May showed a 98.8 per 100,000 (0.1%) incidence of TD among gastroparesis patients treated with metoclopramide.
 - Supports safety profile of only approved molecule in US to treat symptoms of acute and recurrent diabetic gastroparesis.
- **Evoke continues to expand GIMOTI access expansion/sales channel partnerships**
 - Percentage of inbound prescriptions increased with the start of a pilot program with vitaCare Prescription Services, a wholly owned subsidiary of GoodRx, that began in February 2022.
 - vitaCare helps patients understand coverage and identify available savings opportunities and facilitates communications between providers and payors.
- **Company improved cash position.**
 - Company utilized its “at-the-market” (ATM) program to raise proceeds of approximately \$7.1 million, net of commissions and fees.
 - Cash extends the Company’s cash runway into the second quarter of 2023.

Second Quarter 2022 Financial Review

For the second quarter of 2022, net product sales were approximately \$462,000 compared with \$237,000 during the second quarter of 2021, and the net loss was approximately \$2.2 million, or \$0.71 cents per share, compared with \$2.3 million, or \$0.85 per share, for the second quarter of 2021. The increase in net sales was due to a higher number of GIMOTI prescriptions.

Research and development expenses totaled approximately \$191,000 for the second quarter of 2022 compared with approximately \$195,000 for the second quarter of 2021.

For the second quarter of 2022, selling, general and administrative expenses were approximately \$2.3 million compared with \$2.1 million for the second quarter of 2021. We continue to expect that selling, general and administrative expenses will increase in the future as we continue to progress with the commercialization of GIMOTI and we reimburse Eversana from the net profits attained from the sales of GIMOTI.

Total operating expenses for the second quarter of 2022 were approximately \$2.6 million compared with \$2.4 million for the same period of 2021.

As of June 30, 2022, cash and cash equivalents were approximately \$13.5 million. Evoke believes, based on its current operating plan, that its existing cash and cash equivalents, as well as 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, August 10, 2022, at 4:30 p.m. ET to discuss the results. The dial-in numbers for the conference call are (800) 343-4849 and (203) 518-9848 for international callers. The conference ID number is EVOKQ222

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-104672345100289> Follow Evoke Pharma on Facebook: <https://www.facebook.com/Evoke-Pharma-Inc-131313647029724>

Follow Evoke Pharma on LinkedIn: <https://www.linkedin.com/company/evoke-pharma/>

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 ($\geq 5\%$) 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

Invoke 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 and enrollments in vitaCare and EvokeAssist; Evoke’s commercialization plans, including its plans to increase awareness of and access to 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; 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; Evoke’s ability to fund its operating plans with our current capital resources and ability to obtain additional financing as needed to support its operations; 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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Source: Evoke Pharma, Inc.

Evoke Pharma, Inc.

Balance Sheet

	June 30, 2022 <u>(Unaudited)</u>	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	\$ 13,450,949	\$ 9,144,710
Accounts receivable, net	365,643	295,193
Prepaid expenses	307,919	923,746
Inventory	268,334	185,534
Other current assets	11,551	11,551
Total current assets	<u>14,404,396</u>	<u>10,560,734</u>
Operating lease right-of-use asset	—	12,428
Total assets	<u>\$ 14,404,396</u>	<u>\$ 10,573,162</u>
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 824,481	\$ 874,028
Accrued compensation	528,665	519,317
Operating lease liability	—	12,428
Total current liabilities	<u>1,353,146</u>	<u>1,405,773</u>
Long-term liabilities		
Note payable	5,000,000	5,000,000
Accrued interest payable	860,240	612,295
Total long-term liabilities	<u>5,860,240</u>	<u>5,612,295</u>
Total liabilities	7,213,386	7,018,068
Stockholders' equity:		
Common stock	334	3,266
Additional paid-in capital	119,020,734	110,974,841
Accumulated deficit	<u>(111,830,058)</u>	<u>(107,423,013)</u>
Total stockholders' equity	<u>7,191,010</u>	<u>3,555,094</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 14,404,396</u>	<u>\$ 10,573,162</u>

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net product sales	\$ 461,795	\$ 236,635	\$ 880,175	\$ 327,056
Operating expenses:				
Cost of goods sold	67,774	68,253	90,535	133,004
Research and development	191,478	195,229	233,194	473,054
Selling, general and administrative	2,315,175	2,142,149	4,720,251	4,480,443
Total operating expenses	<u>2,574,427</u>	<u>2,405,631</u>	<u>5,043,980</u>	<u>5,086,501</u>
Loss from operations	(2,112,632)	(2,168,996)	(4,163,805)	(4,759,445)
Other income (expense):				
Forgiveness of paycheck protection loan and accrued interest	—	—	—	105,130
Interest income	3,910	3,011	4,705	6,174
Interest expense	(124,658)	(124,658)	(247,945)	(247,997)
Total other income (expense)	<u>(120,748)</u>	<u>(121,647)</u>	<u>(243,240)</u>	<u>(136,693)</u>
Net loss	<u>\$ (2,233,380)</u>	<u>\$ (2,290,643)</u>	<u>\$ (4,407,045)</u>	<u>\$ (4,896,138)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.71)</u>	<u>\$ (0.85)</u>	<u>\$ (1.50)</u>	<u>\$ (1.85)</u>
Weighted-average shares used to compute basic and diluted net loss per share	<u>3,156,925</u>	<u>2,698,833</u>	<u>2,944,183</u>	<u>2,647,669</u>