

**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 12, 2021

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 May 12, 2021, Evoke Pharma, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2021. 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 May 12, 2021

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: May 12, 2021

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



Investor Contact:
 The Ruth Group
 Christine Petraglia / James Salierno
 Tel: 917-633-8980 / 973-255-8361
cpetraglia@theruthgroup.com /
jsalierno@theruthgroup.com

Media Contact:
 The Ruth Group
 Annika Parrish
 Tel: 720-412-9042
aparrish@theruthgroup.com

Evoked Pharma Reports First Quarter 2021 Financial Results

Nearly 293% growth of product sales, 235% growth of prescriptions and 87% increase in new prescribers for Gimoti®

New notice of allowance from USPTO to expand Gimoti patent estate

SOLANA BEACH, CA, May 12, 2021 – Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused primarily on treatments for gastrointestinal (GI) diseases, today announced its financial results for the first quarter ended March 31, 2021 and recent corporate developments.

“Our commercialization efforts continue to lay the foundation to generate increased sales revenue through our focused strategies with targeted gastroenterologist offices,” stated David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. “The feedback from physicians and the many anecdotal stories of patient satisfaction remain strong. This reinforces our message with health care providers that Gimoti offers an important advantage in treating patients that have erratic absorption of oral medications, as it is currently the only outpatient non-oral treatment option to help improve the quality of life for patients suffering with diabetic gastroparesis.”

First Quarter 2021 Developments and Recent Progress:

- Expanded revenue, marketing campaigns and prescriber base for GIMOTI with our commercial partner, EVERIANA
 Completed Medicaid registration process to allow claims submissions for Gimoti
 Government payer coverage makes up nearly 40% of filled prescriptions in Q1, 2021
 - New prescribers continue to expand rapidly
 4Q 2020: 45
 1Q 2021: 84 (87% increase)
 April 2021: 44 (Single month comparable to entire Q4, 2020)
 - Of the patients who had been prescribed Gimoti and had the opportunity, 73% receive a refill
-

- In January 2021, we announced positive data from market research study which indicated 79% and 89% of target and non-target gastroenterologists, respectively, intend to prescribe Gimoti
- Bolstered capital position through a \$14.4 million capital raise
- Notice of Allowance from United States Patent and Trademark Office for a Method of Use Patent with Claims Covering Gimoti
Expected to be granted and Orange Book listable at FDA in near term

First Quarter 2021 Financial Review

For the first quarter of 2021, net sales were approximately \$90,000 and the net loss was approximately \$2.6 million, or \$0.08 per share, compared to a net loss of approximately \$1.8 million, or \$0.07 per share for the first quarter of 2020. This increase was primarily due to costs associated with the commercial launch of GIMOTI.

Research and development expenses totaled approximately \$0.3 million for the first quarter of 2021 compared to approximately \$0.5 million for the first quarter of 2020.

For the first quarter of 2021, selling, general and administrative expenses were approximately \$2.3 million compared to approximately \$1.3 million for the first quarter of 2020.

We 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 first quarter of 2021 were approximately \$2.7 million compared to total operating expenses of approximately \$1.8 million for the same period of 2020.

As of March 31, 2021, the Company's cash and cash equivalents were approximately \$18.2 million, which includes approximately \$13.1 million in net proceeds raised from our common stock offering in January 2021. We expect sufficient runway to fund our operations into the first quarter of 2022.

Evoke will host a conference call today, May 12, 2021, at 4:30 p.m. ET to discuss the results. The dial-in numbers for the conference call are (877) 473-1186 for domestic callers and (918) 922-6138 for international callers. The conference ID number is 7196028.

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.

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.

About EVERSANA Life Science Services, LLC

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.

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: Evoke's commercialization plans, including potential reimbursement from government payors and its plans to increase the number of new prescribers; potential future prescribing trends for GIMOTI based on the market research survey of healthcare professionals or the Company's marketing efforts; the size of the gastroparesis market; and the possibility that gastroenterologists will agree that GIMOTI offers distinct advantages over other treatments for diabetes 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: 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; the results of the market survey may not predict prescribing trends by doctors or acceptance by patients, and are not intended to reflect or imply actual prescriptions or sales to date; 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; Evoke's ability to obtain and maintain intellectual property protection for GIMOTI; and other risks 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.

##

(Financial Statements to Follow)

Evoke Pharma, Inc.

Condensed Balance Sheets

	March 31, 2021	December 31, 2020
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 18,185,974	\$ 8,068,939
Accounts receivable, net	127,795	23,311
Prepaid expenses	614,508	921,762
Inventory	236,044	236,480
Other current assets	11,703	30,300
Total current assets	19,176,024	9,280,792
Operating lease right-of-use asset	119,926	141,705
Other assets	—	11,551
Total assets	\$ 19,295,950	\$ 9,434,048
Liabilities and stockholders' (deficit) equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 691,225	\$ 1,273,572
Accrued compensation	428,794	1,016,232
Operating lease liability	119,926	141,705
Paycheck protection program loan	—	104,168
Milestone payable	5,000,000	5,000,000
Other current liabilities	9,038	—
Total current liabilities	6,248,983	7,535,677
Long-term liabilities		
Note payable	5,000,000	5,000,000
Accrued interest payable	235,583	112,994
Total long-term liabilities	5,235,583	5,112,994
Total liabilities	11,484,566	12,648,671
Stockholders' (deficit) equity:		
Common stock	3,237	2,662
Additional paid-in capital	109,298,703	95,667,776
Accumulated deficit	(101,490,556)	(98,885,061)
Total stockholders' (deficit) equity	7,811,384	(3,214,623)
Total liabilities and stockholders' (deficit) equity	\$ 19,295,950	\$ 9,434,048

Evoke Pharma, Inc.

Condensed Statements of Operations

	Three Months Ended March 31,	
	2021	2020
Net product sales	\$ 90,421	\$ —
Operating expenses:		
Cost of goods sold	64,751	—
Research and development	277,825	463,853
Selling, general and administrative	2,338,295	1,329,834
Total operating expenses	2,680,871	1,793,687
Loss from operations	(2,590,450)	(1,793,687)
Other income (expense):		
Forgiveness of paycheck protection loan and accrued interest	105,130	—
Interest income	3,164	3,378
Interest expense	(123,339)	—
Total other income (expense)	(15,045)	3,378
Net loss	\$ (2,605,495)	\$ (1,790,309)
Net loss per share of common stock, basic and diluted	\$ (0.08)	\$ (0.07)
Weighted-average shares used to compute basic and diluted net loss per share	31,158,065	24,439,881