

**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): September 30, 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 November 10, 2021, Evoke Pharma, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 issues on November 10, 2021
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 10, 2021

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



Investor Contact:
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Evoke Pharma Reports Third Quarter 2021 Financial Results

SOLANA BEACH, CA, November 10, 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 quarter ended September 30, 2021 and recent corporate developments.

“Through our hard work and valued partnership with Eversana, we continued to increase in-person access to physicians during the third quarter of 2021. We have also successfully executed on strategic commercial initiatives to expand awareness and adoption of GIMOTI. As a result, we are pleased to observe continued refill rates, sales growth, and prescribing physicians trending in a positive direction.” stated David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. “The overarching goal is delivering GIMOTI to diabetic gastroparesis patients desperately wanting new options to treat this critical unmet medical need and helping to improve their lives. We will continue working tirelessly to fulfill this mission and in doing so, helping GIMOTI further achieve commercial success.”

Third Quarter 2021 Developments and Recent Progress:

- New prescribers continued to demonstrate strong growth, with an additional 84 added in the third quarter of 2021.
 - Since launch, of the patients who had been prescribed GIMOTI and had additional refills available, 62% have received a refill.
 - Our first in-person National Sales Meeting was held in September, attended by Evoke’s management, Eversana’s sales and marketing representatives, and guest speakers.
 - A patient and physician experience program was launched in July 2021 to expand awareness and trial of GIMOTI among non-prescribing healthcare providers.
 - Positive data from a recent market research study indicated 90% of targeted gastroenterologists intend to prescribe GIMOTI compared to 79% in previous study.
 - We received the PM360’s Trailblazer Initiative Award for Innovation in Healthcare Marketing for GIMOTI in collaboration with commercial partner EVERSANA.
 - An exhibit booth was hosted by Evoke with EVERSANA at American College of Gastroenterology 2021 Annual Scientific Meeting.
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Third Quarter 2021 Financial Review

The net loss for the third quarter of 2021 was approximately \$2.0 million, or \$0.06 per share, compared to a net loss of approximately \$2.1 million, or \$0.08 per share, for the third quarter of 2020.

For the third quarter of 2021, net product sales were approximately \$930,000 compared to approximately \$237,000 during the second quarter of 2021. The increase in net sales includes a \$683,000 sale to a third party for research purposes and a higher number of GIMOTI prescriptions. There were no net product sales during the three months ended September 30, 2020 as commercial sales began in October 2020.

Research and development expenses totaled approximately \$0.1 million for the third quarter of 2021 compared to approximately \$0.2 million for the third quarter of 2020.

For the third quarter of 2021, selling, general and administrative (SG&A) expenses were approximately \$2.6 million compared to approximately \$1.9 million for the third quarter of 2020. The increase in SG&A was primarily related to commercialization activities. We expect that selling, general and administrative expenses will increase in the future as we continue to commercialize GIMOTI and we reimburse Eversana from the net profits attained from the sales of GIMOTI.

Total operating expenses for the third quarter of 2021 were approximately \$2.8 million compared to total operating expenses of approximately \$2.1 million for the same period of 2020.

As of September 30, 2021, the Company's cash and cash equivalents were approximately \$11.1 million. We expect our cash and cash equivalents as of September 30, 2021, as well as cash flows from future net sales of Gimoti, will be sufficient to fund our operations through the third quarter of 2022.

Conference Call Details

Evoke will host a conference call today, November 10, 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 1228707.

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.

Gimoti Product website: <https://www.GimotiRx.com>

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 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.
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- 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 and the sufficiency of Evoke's capital resources to fund its operations through the third quarter of 2022. 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 patient and physician experience program may not increase the number of prescriptions of GIMOTI; the results of the market research study 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; 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; Evoke's ability to obtain, maintain and successfully enforce 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.

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(Financial Statements to Follow)

Evoke Pharma, Inc.

Balance Sheet

	September 30, 2021	December 31, 2020
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 11,141,908	\$ 8,068,939
Accounts receivable, net	222,166	23,311
Prepaid expenses	—	921,762
Inventory	225,217	236,480
Other current assets	11,551	30,300
Total current assets	11,600,842	9,280,792
Operating lease right-of-use asset	49,117	141,705
Other assets	—	11,551
Total assets	\$ 11,649,959	\$ 9,434,048
Liabilities and stockholders' equity (deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 530,528	\$ 1,273,572
Accrued compensation	810,790	1,016,232
Operating lease liability	49,117	141,705
Paycheck protection program loan	—	104,168
Milestone payable	—	5,000,000
Total current liabilities	1,390,435	7,535,677
Long-term liabilities		
Note payable	5,000,000	5,000,000
Accrued interest payable	486,268	112,994
Total long-term liabilities	5,486,268	5,112,994
Total liabilities	6,876,703	12,648,671
Stockholders' equity (deficit):		
Common stock	3,266	2,662
Additional paid-in capital	110,520,641	95,667,776
Accumulated deficit	(105,750,651)	(98,885,061)
Total stockholders' equity (deficit)	4,773,256	(3,214,623)
Total liabilities and stockholders' equity (deficit)	\$ 11,649,959	\$ 9,434,048

Evoke Pharma, Inc.

Statement of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net product sales	\$ 930,449	\$ —	\$ 1,257,505	\$ —
Operating expenses:				
Cost of goods sold	58,435	—	191,439	—
Research and development	81,699	205,032	554,753	6,450,979
Selling, general and administrative	2,635,161	1,874,578	7,115,605	4,387,284
Total operating expenses	2,775,295	2,079,610	7,861,797	10,838,263
Loss from operations	(1,844,846)	(2,079,610)	(6,604,292)	(10,838,263)
Other income (expense):				
Forgiveness of paycheck protection loan and accrued interest	—	—	105,130	—
Interest income	1,421	1,033	7,596	4,896
Interest expense	(126,027)	(50,528)	(374,024)	(53,442)
Total other income (expense)	(124,606)	(49,495)	(261,298)	(48,546)
Net loss	\$ (1,969,452)	\$ (2,129,105)	\$ (6,865,590)	\$ (10,886,809)
Net loss per share of common stock, basic and diluted	\$ (0.06)	\$ (0.08)	\$ (0.21)	\$ (0.43)
Weighted-average shares used to compute basic and diluted net loss per share	32,542,481	26,146,220	32,028,850	25,191,359