# 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): November 10, 2020

# EVOKE PHARMA, INC.

	act Name of Registrant as Specified in it	,
Delaware (State or Other Jurisdiction of Incorporation)	001-36075 (Commission File Number)	20-8447886 (IRS Employer Identification No.)
420 Stevens Avenue Solana Beach, Ca (Address of Principal Exe	92075 (Zip Code)	
Registrant <sup>2</sup>	's telephone number, including area cod	le: (858) 345-1494
(Former N	ame or Former Address, if Changed Si	nce Last Report.)
		-
Securities 1	registered pursuant to Section 12(b) of t	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 General Instruction A.2. below):	led to simultaneously satisfy the filing obl	ligation of the registrant under any of the following provisions (see
<ul> <li>□ Written communications pursuant to Rule 425 under the Sec</li> <li>□ Soliciting material pursuant to Rule 14a-12 under the Exchar</li> <li>□ Pre-commencement communications pursuant to Rule 14d-2</li> <li>□ Pre-commencement communications pursuant to Rule 13e-4</li> </ul>	nge Act (17 CFR 240.14a-12) 2(b) under the Exchange Act (17 CFR 240	
Indicate by check mark whether the registrant is an emerging grothe Securities Exchange Act of 1934 (§240.12b-2 of this chapter	- ·	he Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of
Emerging growth company $\square$		
If an emerging growth company, indicate by check mark if the reaccounting standards provided pursuant to Section 13(a) of the E		ed transition period for complying with any new or revised financial

#### Item 2.02 Results of Operations and Financial Condition.

On November 10, 2020, Evoke Pharma, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2020. 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 November 10, 2020.

#### **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, 2020 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 Jan Medina, CFA Tel: 646-536-7035 jmedina@theruthgroup.com

Media Contact: The Ruth Group Kirsten Thomas Tel: 508-280-6592 kthomas@theruthgroup.com

### **Evoke Pharma Reports Third Quarter 2020 Financial Results**

Gimoti<sup>TM</sup> commercial launch underway

**SOLANA BEACH, CA, November 10, 2020** – Evoke Pharma, Inc. (NASDAQ: EVOK), a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced its financial results for the third quarter ended September 30, 2020 and recent corporate developments.

"The third quarter was marked by preparation for the commercial launch of GIMOTI, which we successfully implemented in early fourth quarter. The launch of GIMOTI to treat symptoms of acute and recurrent diabetic gastroparesis with our commercial partner EVERSANA marked a pivotal event for the Company," said David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. "As a nasally delivered product, GIMOTI has distinct differences over oral formulations of metoclopramide. It is the only outpatient non-oral treatment option to help improve the quality of life for patients suffering with diabetic gastroparesis. Initial prescriptions of GIMOTI have already been filled at the EVERSANA specialty pharmacy through our patient support team at Evoke*AssistTM*. We believe this vital support program will aid both physicians and patients through enrollment, reimbursement, and delivery of GIMOTI directly to the patient. Given the milestones achieved for commercial preparedness, we believe we are in a strong position as we launch GIMOTI and address a significant unmet medical need for millions of patients suffering from diabetic gastroparesis."

#### Third Quarter 2020 Developments and Recent Progress:

- Launched GIMOTI with commercial partner, EVERSANA, in line with prior guidance
- Implemented Evoke Assist, an integrated patient support program
- Appointed Chris Quesenberry as Chief Commercial Officer for GIMOTI through our Commercial partner, EVERSANA
- Built an entire commercial team, including field sales and call center
- Completed manufacturing of the first commercial lot of GIMOTI

#### Third Quarter 2020 Financial Review

For the third quarter of 2020, net loss was approximately \$2.1 million, or \$0.08 per share, compared to a net loss of approximately \$1.6 million, or \$0.07 per share, for the third quarter of 2019.

Research and development expenses totaled approximately \$0.2 million for the third quarter of 2020, compared to approximately \$0.8 million for the third quarter of 2019. The decrease during the three months ended September 30, 2020 was primarily due to the decrease in research and development activity following the GIMOTI NDA approval in June 2020.

For the third quarter of 2020, general and administrative expenses were approximately \$1.9 million compared to approximately \$0.8 million for the third quarter of 2019. The increase during the three months ended September 30, 2020 was primarily due to increased costs associated with our commercialization and selling activities. Of the costs incurred during the third quarter of 2020, approximately \$745,000 were related to commercialization activities.

Total operating expenses for the third quarter of 2020 were approximately \$2.1 million, compared to total operating expenses of approximately \$1.6 million for the third quarter of 2019.

As of September 30, 2020, the Company's cash and cash equivalents were approximately \$6.3 million. The Company expects that its current cash balance will be sufficient to support operations into the second quarter of 2021, without consideration of potential future GIMOTI revenue.

#### About Evoke Pharma, Inc.

Evoke is a specialty pharmaceutical company focused primarily on the commercialization and development of drugs to treat GI disorders and diseases. The Company developed GIMOTI, a nasal spray formulation of metoclopramide, for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adults. GIMOTI is available by prescription through the Evoke*Assist*<sup>TM</sup> patient support center. Visit www.GimotiRx.com for more information.

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. GIMOTI is absorbed in the nasal cavity and bypasses the erratic gastric absorption often seen in gastroparesis patients. Prior to FDA approval to commercially market GIMOTI, metoclopramide was only available in oral and injectable formulations. It remains the only drug currently approved in the United States to treat gastroparesis. Visit <a href="https://www.EvokePharma.com">www.EvokePharma.com</a> for more information.

#### About Gimoti<sup>TM</sup> (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 laryingeal 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 (≥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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

#### 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 size of the gastroparesis market and the potential of GIMOTI to provide an important new alternative to current treatment options. 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, including through the EVERSANA line of credit which is subject to certain customary conditions; the COVID-19 pandemic may 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 Pharm, Inc.**

## **Balance Sheets**

		September 30, 2020 (Unaudited)		
Assets				
Current Assets:	\$	( 200 (5)	¢	
Cash and cash equivalents Prepaid expenses	Ъ	6,280,656 336,432	\$	
Inventory		86,145		
Other current assets		11,551		
Total current assets		6,714,784		
Operating lease right-of-use asset		36,115		
Other assets		30,113		
Total assets	\$	6,750,899	\$	
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Liabilities and stockholders' equity				
Current Liabilities:				
Accounts payable and accrued expenses	\$	765,603	\$	
Accrued compensation		715,423		
Operating lease liability		36,115		
Paycheck protection program loan		104,168		
Milestone payable		5,000,000		
Total current liabilities		6,621,309		
Long-term Liabilities:				
Note payable		2,000,000		
Accrued interest payable		53,005		
Total long-term liabilities		2,053,005		
Total liabilities		8,674,314		
Stockholders' equity:				
Common stock		2,633		
Additional paid-in capital		94,691,151		
Accumulated deficit		(96,617,199)		
Total stockholders' (deficit) equity		(1,923,415)		
Total liabilities and stockholders' (deficit) equity	\$	6,750,899	\$	
Total natifices and stockholders (deficit) equity	<u> </u>	0,730,899	Ψ	

# Evoke Pharma, Inc.

# Statement of Operations (Unaudited)

	Three Months Ended September 30,			Nine Months End September 30,			
		2020		2019		2020	
Operating expenses:							
Research and development	\$	205,032	\$	822,444	\$	6,450,979	\$
General and administrative		1,874,578		814,218		4,387,284	
Total operating expenses		2,079,610		1,636,662		10,838,263	
Loss from operations		(2,079,610)		(1,636,662)		(10,838,263)	
Other income (expense):							
Interest income		1,033		8,597		4,896	
Interest expense		(50,528)		_		(53,442)	
Total other income							
(expense), net		(49,495)		8,597		(48,546)	
Net loss	\$	(2,129,105)	\$	(1,628,065)	\$	(10,886,809)	\$
Net loss per share of common stock, basic and diluted	\$	(0.08)	\$	(0.07)	\$	(0.43)	<u>\$</u>
Weighted-average shares used to compute basic and diluted net							
loss per share		26,146,220		24,128,060		25,191,359	