

**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): March 11, 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 March 11, 2021, Evoke Pharma, Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 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 March 11, 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: March 11, 2021

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



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Evoked Pharma Reports Fourth Quarter and Full Year 2020 Financial Results

Encouraging early traction from GIMOTI™ commercial launch

SOLANA BEACH, CA, March 11, 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 fourth quarter ended December 31, 2020 and recent corporate developments.

“Despite the challenges precipitated by the COVID-19 pandemic, 2020 proved to be a transformative year for Evoke as we initiated the commercial launch of GIMOTI™ for acute and recurrent diabetic gastroparesis with our commercial partner EVERSANA,” stated David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. “We are encouraged by the early traction we are seeing in GIMOTI sales and the feedback we are receiving from gastroenterologists, which was further illustrated by the positive data observed in our market research study. We believe GIMOTI offers a distinct advantage over oral metoclopramide formulations as it is currently the only outpatient non-oral treatment option to help improve the quality of life for patients suffering with diabetic gastroparesis. We look forward to further addressing this significant medical need for the up to 16 million patients suffering from these symptoms as we continue to build sales traction.”

Fourth Quarter 2020 Developments and Recent Progress:

- Developed a patient support HUB and co-pay program called EvokeAssist to coordinate GIMOTI reimbursement and distribution via our exclusive pharmacy distribution program
 - Launched GIMOTI with commercial partner, EVERSANA
 - The typical patient who received GIMOTI is female between 50-64 who has commercial insurance
 - Since launch 65% of dispenses are commercial (either covered by a commercial payer or our co-pay program) and 27% were covered by a Medicare plan.
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- Of the patients who have tried GIMOTI, nearly 40% have had at least one refill
- In January 2021, announced positive data from market research study which indicated 79% and 89% of target and non-target gastroenterologists intend to prescribe GIMOTI
- Bolstered capital position through a \$14.4 million capital raise and extended cash runway into the first quarter of 2022, excluding any future GIMOTI revenue

Fourth Quarter and Full Year 2020 Financial Review

For the fourth quarter of 2020, net sales were approximately \$23,000 and the net loss was approximately \$2.3 million, or \$0.09 per share, compared to a net loss of approximately \$1.4 million, or \$0.06 per share for the fourth quarter of 2019. For the year ended December 31, 2020, the net loss was approximately \$13.2 million, or \$0.52 per share. This compares to a net loss of approximately \$7.1 million, or \$0.32 per share for the full year of 2019. This increase was primarily due to recording a \$5 million expense in June 2020 upon achieving a technology acquisition milestone related to FDA's approval of GIMOTI, along with costs associated with the commercial launch of GIMOTI.

Research and development expenses totaled approximately \$0.1 million for the fourth quarter of 2020 compared to approximately \$0.6 million for the fourth quarter of 2019. For the full year of 2020, research and development expenses were approximately \$6.6 million compared to approximately \$3.4 million in the prior year. This increase in 2020 was primarily due to recording a \$5.0 million expense in June 2020 upon achieving a technology acquisition milestone related to the FDA's approval of GIMOTI.

For the fourth quarter of 2020, selling, general and administrative expenses were approximately \$2.0 million compared to approximately \$0.8 million for the fourth quarter of 2019. For the year ended December 31, 2020, selling, general and administrative expenses were approximately \$6.4 million versus approximately \$3.7 million for the full year of 2019.

Of the total selling, general and administrative expenses incurred during the year ended December 31, 2020, approximately \$2.0 million was related to pre-commercialization and commercialization activities for GIMOTI.

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 fourth quarter of 2020 were approximately \$2.1 million compared to total operating expenses of approximately \$1.4 million for the same period of 2019. For the year ended December 31, 2020, total operating expenses were approximately \$13.1 million compared to approximately \$7.2 million for the full year of 2019.

As of December 31, 2020, the Company's cash and cash equivalents were approximately \$8.1 million, which excludes 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.

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 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.
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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

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: Evoke's commercialization plans, including its plans to increase awareness and access to GIMOTI; 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.

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(Financial Statements to Follow)

Evoke Pharma, Inc.

Balance Sheets

	December 31,	
	2020	2019
Assets		
Current Assets:		
Cash and cash equivalents	\$ 8,068,939	\$ 5,663,833
Accounts receivable, net	23,311	—
Prepaid expenses	921,762	581,706
Inventory	236,480	—
Other current assets	30,300	—
Total current assets	9,280,792	6,245,539
Operating lease right-of-use asset	141,705	138,538
Other assets	11,551	11,551
Total assets	\$ 9,434,048	\$ 6,395,628
Liabilities and stockholders' (deficit) equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,273,572	\$ 1,033,383
Accrued compensation	1,016,232	843,162
Operating lease liability	141,705	138,538
Paycheck protection program loan	104,168	—
Milestone payable	5,000,000	—
Total current liabilities	7,535,677	2,015,083
Long-term Liabilities:		
Note payable	5,000,000	—
Accrued interest payable	112,994	—
Total long-term liabilities	5,112,994	—
Total liabilities	12,648,671	2,015,083
Stockholders' (deficit) equity:		
Common stock	2,662	2,443
Additional paid-in capital	95,667,776	90,108,492
Accumulated deficit	(98,885,061)	(85,730,390)
Total stockholders' (deficit) equity	(3,214,623)	4,380,545
Total liabilities and stockholders' (deficit) equity	\$ 9,434,048	\$ 6,395,628

Evoke Pharma, Inc.

Statements of Operation

	Year Ended December 31,	
	2020	2019
Net product sales	\$ 23,020	\$ —
Operating expenses:		
Cost of goods sold	86,712	—
Research and development	6,554,825	3,416,466
Selling, general and administrative	6,428,832	3,737,987
Total operating expenses	13,070,369	7,154,453
Loss from operations	(13,047,349)	(7,154,453)
Other income (expense):		
Interest income	5,672	28,798
Interest expense	(112,994)	—
Total other income (expense)	(107,322)	28,798
Net loss	(13,154,671)	(7,125,655)
Net loss per share of common stock, basic and diluted	\$ (0.52)	\$ (0.32)
Weighted-average shares used to compute basic and diluted net loss per share	25,492,169	22,296,089