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 8, 2022

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	001-36075	20-8447886
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

420 Stevens Avenue, Suite 370 Solana Beach, California	92075
(Address of Principal Executive Offices)	(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	Trading symbol	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	EVOK	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 8, 2022, Evoke Pharma, Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 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 issues on March 8, 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: March 8, 2022

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

Exhibit 99.1

Investor Contact:
Daniel-Kontoh-Boateng
DKB Partners
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Evoke Pharma Reports Fourth Quarter and Full Year 2021 Financial Results

Fourth-quarter net product sales from prescriptions increased by 46% to $361,000 versus Q3
Easing of COVID-19 restrictions helped fuel higher sales, increased face-to-face meetings with healthcare professionals

SOLANA BEACH, Calif., March 8, 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 fourth quarter and full year ended December 31, 2021, and recent corporate developments.

“We are happy to report that, by several key metrics, we showed encouraging progress over the course of 2021—especially during the fourth quarter—and continuing into 2022 by calling attention to GIMOTI’s value proposition,” said David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. “Our net product sales from prescriptions increased sequentially by 46%, to $361,000 in the fourth quarter of 2021 from $247,000 in the third quarter. In addition, the number of GIMOTI prescribers increased by approximately 23%, to 425 healthcare providers (HCPs) through December 31, 2021, from 345 through September 30, 2021. This metric continues to increase reaching 499 prescribers as of the end of February. We are encouraged by the positive trends we are seeing in these future revenue indicators for GIMOTI and look forward to continued success in the market. Together with Eversana, we look forward to employing more strategies to ensure GIMOTI is reaching the patients who need it most.”

Fourth Quarter 2021 Developments and Recent Progress:

- **Conducted higher number of in-person meetings with HCPs in many areas of the U.S.**

  Eased COVID-19 restrictions on HCPs in many areas of U.S. allowed for more face-to-face meetings with gastroenterologists, primary care physicians, physician’s assistants and nurse practitioners

- **Judicious increases in GIMOTI samples distributed to HCPs to allow for greater trial which has led to higher prescription sales**

  Recent national sales meeting provided valuable insights in gaining additional physician and patient experience with GIMOTI

- **Extended strategic collaboration with EVERSANA to commercialize and distribute GIMOTI within the U.S.**

  Amended agreement extends term and increases the percentage of the net product profit retained by Evoke

  Accelerates the reimbursement of commercialization costs to EVERSANA after the product breaks even on a monthly basis

- **Expanding strategic outreach to state pharmacy programs and specialty pharmacy.**

  New York State Medicaid approval of GIMOTI with confirmation of diabetes diagnosis only

  Initial pilot program for automated Electronic Medical Record (EMR) prescription submission showing impressive follow through with increase in prescriptions and reimbursement

Fourth Quarter and Full Year 2021 Financial Review

For the fourth quarter of 2021, net product sales were approximately $361,000 compared with $23,000 during the fourth quarter of 2020, the first quarter of Gimoti's launch, and the net loss was approximately $1.7 million, or $0.05 cents per share compared with $2.3 million, or $0.09 per share, for the fourth quarter of 2020. For the year ended December 31, 2021, net product sales were approximately $1.6 million compared with approximately $23,000 for the year ended December 31, 2020, and the net loss was approximately $8.5 million, or $0.27 per share, compared with a net loss of $13.2 million, or $0.52 per share, for the year ended December 31, 2020. The year-over-year increase in revenue and reduction in net loss were due to higher net product sales in 2021, including approximately $718,000 of GIMOTI sold to third parties for research purposes, and, to a lesser extent, higher prescription sales in the second half of 2021. In addition, during 2020, we incurred a $5 million milestone expense upon receiving FDA's approval of Gimoti in June 2020.

Research and development expenses totaled approximately $36,000 for the fourth quarter of 2021 compared with $0.1 million for the fourth quarter of 2020. For the full year of 2021, research and development expenses were approximately $0.6 million compared with approximately $6.6 million for the prior year. Since receiving FDA approval of GIMOTI in June 2020, Evoke's research and development costs have decreased and shifted to commercialization and selling costs. For the fourth quarter of 2021, selling, general and administrative expenses were approximately $1.7 million compared with $2.0 million for the fourth quarter of 2020. For the year ended December 31, 2021, selling, general and administrative expenses were approximately $8.9 million versus approximately $6.4 million for the year ended December 31, 2020. The increase in SG&A costs year-over-year resulted primarily from shifting personnel costs from research and development to commercialization costs, along with higher marketing, royalty and Eversana profit sharing costs.

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 2021 were approximately $1.9 million compared with $2.2 million for the same period of 2020. For the year ended December 31, 2021, total operating expenses were approximately $9.8 million compared with approximately $13.1 million for the full year of 2020.

As of December 31, 2021, cash and cash equivalents were approximately $9.1 million. We believe, based on our current operating plan, that our existing cash and cash equivalents, as well as future cash flows from net product sales of GIMOTI, will be sufficient to fund our operations into the first quarter of 2023.

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 (≥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

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: potential future prescribing trends for GIMOTI based on Evoke’s or EVERSANA’s marketing efforts; 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; 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 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 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.

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(Financial Statements to Follow)

Evoke Pharma, Inc.

Balance Sheet

	December 31, 2021	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 9,144,710	$ 8,068,939
Accounts receivable, net	295,193	23,311
Prepaid expenses	923,746	921,762
Inventory	185,534	236,480
Other current assets	11,551	30,300
Total current assets	10,560,734	9,280,792
Operating lease right-of-use asset	12,428	141,705
Other assets	—	11,551
Total assets	$ 10,573,162	$ 9,434,048
Liabilities and stockholders' equity (deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 874,028	$ 1,273,572
Accrued compensation	519,317	1,016,232
Operating lease liability	12,428	141,705
Paycheck protection program loan	—	104,168
Milestone payable	—	5,000,000
Total current liabilities	1,405,773	7,535,677
Long-term liabilities		
Note payable	5,000,000	5,000,000
Accrued interest payable	612,295	112,994
Total long-term liabilities	5,612,295	5,112,994
Total liabilities	7,018,068	12,648,671
Stockholders' equity (deficit):		
Common stock	3,266	2,662
Additional paid-in capital	110,974,841	95,667,776
Accumulated deficit	(107,423,013)	(98,885,061)
Total stockholders' equity (deficit)	3,555,094	(3,214,623)
Total liabilities and stockholders' equity (deficit)	$ 10,573,162	$ 9,434,048

Evoke Pharma, Inc.

Statement of Operations

	Year Ended	
	2021	**2020**
Net product sales	$ 1,618,076	$ 23,020
Operating expenses:		
Cost of goods sold	328,118	86,712
Research and development	590,476	6,554,825
Selling, general and administrative	8,851,129	6,428,832
Total operating expenses	9,769,723	13,070,369
Loss from operations	(8,151,647)	(13,047,349)
Other income (expense):		
Forgiveness of paycheck protection loan and accrued interest	105,130	—
Interest income	8,615	5,672
Interest expense	(500,050)	(112,994)
Total other income (expense)	(386,305)	(107,322)
Net loss	$ (8,537,952)	$ (13,154,671)
Net loss per share of common stock, basic and diluted	$ (0.27)	$ (0.52)
Weighted-average shares used to compute basic and diluted net loss per share	32,185,758	25,492,169