Evoke Pharma Reports Record Third Quarter 2022 Financial Results

November 9, 2022

80% increase in GIMOTI® net revenue over Q2 2022
56% increase of GIMOTI prescription fills in Q3 compared to Q2
13% increase of new prescribers of GIMOTI over Q2

SOLANA BEACH, Calif., Nov. 09, 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 third quarter ended September 30, 2022 and recent corporate developments.

“Evoke delivered record financial and operating results based on the key metrics we use to gauge the overall strength and value of our business,” said David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. “Net product sales of GIMOTI during the third quarter of 2022 grew 80% to approximately $832,000 compared to the second quarter of 2022. Evoke also recorded an increase of 56% in GIMOTI prescriptions dispensed in Q3 compared to Q2.”

“During the third quarter, we completed the transition of our reimbursement program to vitaCare, a wholly owned subsidiary of GoodRx. Inbound prescriptions during Q3 increased 32% over Q2 2022. In addition, the number of GIMOTI prescribers increased to a record 143, which represents a 13% increase over Q2. GIMOTI had 812 cumulative new prescribers as of September 30, an increase of 21% over Q2 2022. As we approach 2023, we are highly encouraged and motivated by our metrics in all categories and we look forward to continuing our mission to improve the quality of life for patients suffering from diabetic gastroparesis,” Mr. Gonyer concluded.

Third Quarter 2022 Developments and Recent Progress:

- **Company received Notice of Allowance from USPTO for a patent related to GIMOTI**
  - Entitled “Treatment of Moderate and Severe Gastroparesis,” the patent expires in 2037, and protects Phase 3 clinical trial outcomes data that shows efficacy with nasal metoclopramide formulations for persons suffering from moderate-to-severe diabetic gastroparesis.
- **New Patient Experience Survey Reported Positive Findings for GIMOTI**
  - Survey conducted with 201 gastroparesis patients.
  - Patients reported the greatest symptom improvement and ease of use with Gimoti compared to competing products (i.e., oral or liquid forms of metoclopramide, and Domperidone).
  - Similar or better side effect profile compared to competing products.
  - Similar to clinical trial findings for specific symptom improvement, patients reported the highest nausea relief and abdominal pain relief with Gimoti compared to competing products.
- **Launched a telehealth solution for patients with UpScriptHealth partnership**
  - Allows patients without regular access to care due to their remote location, lack of transportation, affordability, or work schedule to receive care via a telehealth option.
  - Makes consultations rapidly available and allows for treatment initiation within just a few days, if medically appropriate.
- **GIMOTI nominated as a finalist for Healio Disruptive Innovator of the Year Award**
  - GIMOTI selected among other novel gastroenterology products from six major pharmaceutical companies.
  - Nomination at the 2022 American College of Gastroenterology Scientific Meeting further highlights the novelty of a disruptive non-oral treatment for a disease where traditional oral treatments are noted to be unreliable.

Third Quarter 2022 Financial Review

For the third quarter of 2022, net sales were approximately $832,000 compared with approximately $462,000 in the second quarter of 2022, an increase of approximately 80%. Net sales for the third quarter of 2021 were approximately $247,000, which excludes approximately $683,000 sold to a third party for research purposes. The increase in net sales sequentially and year over year was due to higher number of GIMOTI prescriptions. Net loss was approximately $2.0 million or $0.60 per share in the third quarter of 2022, compared with approximately $2.2 million or $0.71 per share in the second quarter of 2022. Net loss for the third quarter of 2021 was approximately $2.0 million or $0.73 per share. Research and development (R&D) expenses for the three months ended September 30, 2022 were approximately $40,000 compared with approximately $191,000 for the three months ended June 30, 2022 and approximately $82,000 for the third quarter of 2021. R&D expenses in the second quarter of 2022 were higher as a result of increased, non-recurring manufacturing testing.

For the third quarter of 2022, selling, general and administrative (SG&A) expenses were approximately $2.6 million compared with $2.3 million for the second quarter of 2022. SG&A expenses were essentially unchanged from the third quarter of 2021. Total operating expenses for the third quarter of 2022 were approximately $2.7 million compared with $2.6 million for the second quarter of 2022 and approximately $2.8 million for the third quarter of 2021.

As of September 30, 2022, the company's cash and cash equivalents were approximately $12.4 million. Based on the company's current operating plan, it believes that existing cash and cash equivalents as well as anticipated future cash flows from net product sales of GIMOTI will be sufficient to fund operations into the second quarter of 2023.

Conference Call Information

Management will host a conference call on Wednesday, November 9, 2022, at 4:30 p.m. ET to discuss the results. The dial-in numbers for the conference call are **(800) 245-3047 and (203) 518-9765 for international callers. The conference ID number is EVOKQ322.**

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

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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: the potential of GIMOTI to improve the quality of life for patients suffering from diabetic gastroparesis; potential future prescribing trends for GIMOTI; the anticipated scope and term of any patent protection for 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 maintain its existing commercial services agreement with EVERSANA or, if it is terminated or Evoke otherwise elects to do so, retain an alternative organization, or develop its own sales and marketing capability, to commercialize and distribute 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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Evoke Pharma, Inc.
Condensed Balance Sheets

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 12,350,024	$ 9,144,710
Accounts receivable, net	674,970	295,193
Prepaid expenses	—	923,746
Inventory	220,304	185,534
Other current assets	11,551	11,551
Total current assets	13,256,849	10,560,734
Operating lease right-of-use asset	153,671	12,428
Total assets	$ 13,410,520	$ 10,573,162
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 1,020,690	$ 874,028

Accrued compensation	716,993	519,317
Operating lease liability	140,300	12,428
Total current liabilities	1,877,983	1,405,773
Long-term liabilities		
Operating lease liability, non-current	13,371	—
Note payable	5,000,000	5,000,000
Accrued interest payable	986,268	612,295
Total long-term liabilities	5,999,639	5,612,295
Total liabilities	7,877,622	7,018,068
Stockholders' equity:		
Common stock, $0.0001 par value; authorized shares - 50,000,000; issued and outstanding shares - 3,343,070 and 2,721,373 at September 30, 2022 and December 31, 2021, respectively	334	272
Additional paid-in capital	119,376,486	110,977,835
Accumulated deficit	(113,843,922)	(107,423,013)
Total stockholders' equity	5,532,898	3,555,094
Total liabilities and stockholders' equity	$ 13,410,520	$ 10,573,162

Evoke Pharma, Inc.
Statement of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Net product sales	$ 832,100	$ 930,449	$ 1,712,275	$ 1,257,505
Operating expenses:				
Cost of goods sold	89,775	58,435	180,310	191,439
Research and development	40,388	81,699	273,582	554,753
Selling, general and administrative	2,614,488	2,635,161	7,334,738	7,115,605
Total operating expenses	2,744,651	2,775,295	7,788,630	7,861,797
Loss from operations	(1,912,551)	(1,844,846)	(6,076,355)	(6,604,292)
Other income (expense):				
Forgiveness of paycheck protection loan and accrued interest	—	—	—	105,130
Interest income	24,714	1,421	29,419	7,596
Interest expense	(126,027)	(126,027)	(373,973)	(374,024)
Total other income (expense)	(101,313)	(124,606)	(344,554)	(261,298)
Net loss	$ (2,013,864)	$ (1,969,452)	$ (6,420,909)	$ (6,865,590)
Net loss per share of common stock, basic and diluted	$ (0.60)	$ (0.73)	$ (2.09)	$ (2.57)
Weighted-average shares used to compute basic and diluted net loss per share	3,343,070	2,711,871	3,077,145	2,669,070

Source: Evoke Pharma, Inc.