Evoke Pharma Reports Second Quarter 2021 Financial Results

August 12, 2021

Approximately 162% growth in product sales, 152% growth in prescriptions and 57% increase in new prescribers for Gimoti®

Extends cash runway into third quarter of 2022

SOLANA BEACH, Calif., Aug. 12, 2021 (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 second quarter that ended June 30, 2021 which includes recent corporate developments.

"Through our continuing commercial expansion, increasing in-person access to physicians, and growing visibility within the gastroparesis community, we are encouraged by the momentum achieved in the second quarter," stated David A. Gonyer, R.Ph., President and CEO of Evoke Pharma. "Notably, we continued to observe positive trends in refill rates, sales growth, and prescribing physicians, affirming our belief that we are gaining traction among new doctors and patients. As we enter the second half of the year, we look forward to driving our commercial and marketing initiatives forward and establishing GIMOTI as the preferred treatment option for patients suffering from diabetic gastroparesis."

Second Quarter 2021 Developments and Recent Progress:

- New prescribers continued to demonstrate strong growth, rising from 84 during the first quarter of 2021 to 132 in the second quarter of 2021
- Of the patients who had been prescribed GIMOTI and had the opportunity, 61% have received a refill
- Launched a patient and physician experience program in July 2021 to expand awareness and trial of GIMOTI among non-prescribing healthcare providers
- Initiated the first wave of our social media campaign to reach patients directly with education about diabetic gastroparesis
- Announced positive data from second market research study which indicated 90% of targeted gastroenterologists intend to prescribe GIMOTI; compared to 79% in previous study
- New patent issued from the USPTO and listed in the U.S. Food and Drug Administration's (FDA) Orange Book
- Appointed Vickie Reed, an experienced financial leader in the biotechnology industry, to our Board of Directors
- Announced membership into the International Foundation for Gastrointestinal Disorders

Second Quarter 2021 Financial Review

The net loss for the second quarter of 2021 was approximately $2.3 million, or $0.07 per share, compared to a net loss of approximately $7.0 million, or $0.28 per share, for the second quarter of 2020. During the second quarter of 2020 we expensed $5.0 million upon achieving a technology acquisition milestone related to FDA's approval of Gimoti.

For the second quarter of 2021, net product sales were approximately $237,000 compared to approximately $90,000 during the first quarter of 2021. The increase in net sales was due to a higher number of GIMOTI prescriptions. FDA approved our Gimoti NDA in June 2020 and we began commercial sales in October 2020, so there were no net product sales during the three months ended June 30, 2020.

Research and development expenses totaled approximately $195,000 for the second quarter of 2021 compared to approximately $5.8 million for the second quarter of 2020. The decrease in research and development expenses was due to the achievement of the commercial milestone of GIMOTI receiving FDA approval.

For the second quarter of 2021, selling, general and administrative (SG&A) expenses were approximately $2.1 million compared to approximately $1.2 million for the second 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 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 second quarter of 2021 were approximately $2.4 million compared to total operating expenses of approximately $7.0 million for the same period of 2020.

As of June 30, 2021, the Company's cash and cash equivalents were approximately $16.7 million. We expect our cash and cash equivalents as of June 30, 2021, as well as cash flows from future net sales of Gimoti, will be sufficient to fund our operations into the third quarter of 2022.

Evoke will host a conference call today, August 12, 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 2057948.

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 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.

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 marketing efforts to increase awareness and access to, and prescribing trends for, GIMOTI. 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.

(Financial Statements to Follow)

Evoke Pharma, Inc.
Balance Sheets

	June 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 16,720,939	$ 8,068,939
Accounts receivable, net	198,411	23,311
Prepaid expenses	307,254	921,762
Inventory	234,041	236,480
Other current assets	11,703	30,300
Total current assets	17,472,348	9,280,792
Operating lease right-of-use asset	84,933	141,705
Other assets	—	11,551
Total assets	$ 17,557,281	$ 9,434,048
Liabilities and stockholders' equity (deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 519,001	$ 1,273,572
Accrued compensation	621,476	1,016,232
Operating lease liability	84,933	141,705
Paycheck protection program loan	—	104,168
Milestone payable	5,000,000	5,000,000
Other current liabilities	6,025	—
Total current liabilities	6,231,435	7,535,677
Long-term liabilities		
Note payable	5,000,000	5,000,000
Accrued interest payable	360,240	112,994
Total long-term liabilities	5,360,240	5,112,994
Total liabilities	11,591,675	12,648,671
Stockholders' equity (deficit):		
Common stock	3,244	2,662
Additional paid-in capital	109,743,561	95,667,776
Accumulated deficit	(103,781,199)	(98,885,061)
Total stockholders' equity (deficit)	5,965,606	(3,214,623)
Total liabilities and stockholders' equity (deficit)	$ 17,557,281	$ 9,434,048

Evoke Pharma, Inc.
Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net product sales	$ 236,635	$ —	$ 327,056	$ —
Operating expenses:				
Cost of goods sold	68,253	—	133,004	—
Research and development	195,229	5,782,094	473,054	6,245,946
Selling, general and administrative	2,142,149	1,182,872	4,480,443	2,512,707
Total operating expenses	2,405,631	6,964,966	5,086,501	8,758,653
Loss from operations	(2,168,996)	(6,964,966)	(4,759,445)	(8,758,653)
Other income (expense):				
Forgiveness of paycheck protection loan and accrued interest	—	—	105,130	—
Interest income	3,011	485	6,174	3,863
Interest expense	(124,658)	(2,914)	(247,997)	(2,914)
Total other income (expense)	(121,647)	(2,429)	(136,693)	949
Net loss	$ (2,290,643)	$ (6,967,395)	$ (4,896,138)	$ (8,757,704)
Net loss per share of common stock, basic and diluted	$ (0.07)	$ (0.28)	$ (0.15)	$ (0.35)
Weighted-average shares used to compute basic and diluted net loss per share	32,386,004	24,987,975	31,772,035	24,713,928

Investor Contact:
The Ruth Group
Christine Petraglia
Tel: 917-633-8980
cpetraglia@theruthgroup.com

Media Contact:
The Ruth Group
Annika Parrish
Tel: 720-412-9042
aparrish@theruthgroup.com

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