November 13, 2014

Evoke Pharma Reports Third Quarter 2014 Results

SOLANA BEACH, Calif., Nov. 13, 2014 (GLOBE NEWSWIRE) -- 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, 2014.

Dave Gonyer, R.Ph., President and CEO, stated, "During the third quarter, we continued to execute our business strategy and remain on track with the clinical development of EVK-001, our lead product candidate for the treatment of symptoms related to diabetic gastroparesis in women. We expect to provide top-line data from our thorough ECG (QT) study by the end of 2014, ahead of our original target date of early 2015. Once this study is finalized, we will have completed one of the two required studies for submission of our New Drug Application to the FDA."

"Looking ahead, we anticipate top-line data to be reported in mid-2015 for our Phase 3 trial in female diabetic gastroparesis patients. We are excited by the potential to bring a novel non-oral treatment to market for female patients that suffer from this debilitating ailment."

Third Quarter 2014 Financial Review

For the third quarter of 2014, net loss was approximately $3.8 million, or $0.63 per share, compared to a net loss of approximately $486,000, or $0.41 per share, for the three-month period ended September 30, 2013. For the nine-month period ended September 30, 2014, net loss was approximately $10.3 million, or $1.71 per share, versus approximately $1.2 million, or $1.06 per share in the nine-month period ended September 30, 2013.

Research and development expenses in the third quarter of 2014 were approximately $3.1 million, compared to approximately $79,000 for the third quarter of 2013. The year-over-year increase in research and development expenses was primarily related to an increase in clinical trial costs associated with the Phase 3 trial and the thorough ECG (QT) study for EVK-001. Research and development expenses were approximately $7.8 million for the nine-month period ended September 30, 2014 compared to approximately $321,000 for the nine-month period ended September 30, 2013.

For the third quarter of 2014, general and administrative expenses were approximately $733,000, compared with approximately $407,000 for the third quarter of 2013. The increase is attributable to an increase in headcount and costs associated with public reporting requirements following the Company's initial public offering in September 2013. For the nine month period ended September 30, 2014, general and administrative expenses were approximately $2.4 million, compared to approximately $700,000 for the nine months ended September 30, 2013.

Total operating expenses for the third quarter of 2014 were approximately $3.8 million, compared to total operating expenses of approximately $486,000 in the third quarter of 2013. For the nine-month period ended September 30, 2014, total operating expenses were approximately $10.2 million, versus approximately $1.0 million for the nine months ended September 30, 2013.

As of September 30, 2014, the Company's cash and cash equivalents were approximately $12.2 million.

Conference Call and Webcast

Evoke will hold a conference call on Thursday, November 13, 2014, at 4:30 p.m. ET to discuss the results. The dial-in numbers are 1-877-407-0789 for domestic callers and 1-201-689-8562 for international callers. The conference ID number for both is 13592498. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at www.evokepharma.com.

After the live webcast, the event will remain archived on Evoke's website for one year. In addition, a telephonic replay of the call will be available until November 20, 2014. The replay dial-in numbers are 1-877-870-5176 for domestic callers and 1-858-384-5517 for international callers. Please use event passcode 13592498.

About Evoke Pharma, Inc.

Evoke Pharma is a specialty pharmaceutical company focused primarily on the development of drugs to treat GI disorders and diseases. The Company is developing EVK-001, a metoclopramide nasal spray for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in women with diabetes mellitus. Diabetic gastroparesis is a GI disorder afflicting millions of sufferers worldwide, in which the stomach takes too long to empty its contents resulting in serious digestive system symptoms. Metoclopramide is the only product currently approved in the United States to treat gastroparesis, and is currently available only in oral and intravenous forms. EVK-001 is a novel formulation of this drug, designed to provide systemic delivery of metoclopramide through intranasal administration.

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 timing of top-line data completion of Evoke's ongoing Phase 3 clinical trial of EVK-001, the potential approval and commercialization of EVK-001 as a new and effective treatment for gastroparesis, the timing of top-line data completion of the thorough ECG study and Evoke's current trials and study serving as a basis for submission of a New Drug Application. 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 risk and uncertainties inherent in Evoke's business, including, without limitation: Evoke is entirely dependent on the success of EVK-001, for which it has commenced a Phase 3 clinical trial, male companion trial and thorough ECG study, and Evoke cannot be certain that it will be able to obtain regulatory approval for, or successfully commercialize, EVK-001; the results observed in female patients with symptoms associated with acute and recurrent diabetic gastroparesis in Evoke's Phase 2b clinical trial of EVK-001 may not be predictive of the safety and efficacy results in the Phase 3 clinical trial; the risk that the results of the thorough ECG study may not replicate the cardiovascular safety profile observed in patients administered with metoclopramide to date; the inherent risks of clinical development of EVK-001, including potential delays in enrollment and completion of clinical trials and studies; Evoke will require substantial additional funding to complete the Phase 3 clinical trial of and potentially commercialize EVK-001 as well as to finance additional development requirements, and may be unable to raise capital when needed; the potential for adverse safety findings relating to EVK-001 to delay or prevent regulatory approval or commercialization; Evoke's reliance on outsourcing arrangements for many of its activities, including clinical development and supply of EVK-001; the ability of Evoke to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of its product candidate and the ability to operate its business without infringing the intellectual property rights of others; competition from other pharmaceutical or biotechnology companies; 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.

Evoke Pharma, Inc.

Condensed Balance Sheets

	September 30, 2014	December 31, 2013
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 12,176,682	$ 24,196,691
Prepaid expenses	1,131,685	234,262
Total current assets	13,308,367	24,430,953
Other assets	82,553	555,505
Total assets	$ 13,390,920	$ 24,986,458
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,049,369	$ 284,915

Accrued compensation	636,098	557,399
Current portion of long-term debt	—	1,442,592
Total current liabilities	1,685,467	2,284,906
Deferred rent expense	14,714	6,830
Long-term debt, net of current portion	—	1,511,461
Total liabilities	1,700,181	3,803,197
Stockholders' equity:		
Common stock	611	610
Additional paid-in capital	44,709,474	43,874,119
Accumulated deficit	(33,019,346)	(22,691,468)
Total stockholders' equity	11,690,739	21,183,261
Total liabilities and stockholders' equity	$ 13,390,920	$ 24,986,458

Evoke Pharma Inc.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	**2013**	**2014**	**2013**
Operating expenses:				
Research and development	$ 3,088,373	$ 78,731	$ 7,815,466	$ 320,558
General and administrative	732,800	406,862	2,420,167	700,489
Total operating expenses	3,821,173	485,593	10,235,633	1,021,047
Loss from operations	(3,821,173)	(485,593)	(10,235,633)	(1,021,047)
Other income (expense):				
Interest income	1,725	629	8,995	2,850
Interest expense	(5,906)	(39,940)	(101,240)	(119,570)
Change in fair value of warrant liability	—	39,000	—	(82,000)
Total other income (expense)	(4,181)	(311)	(92,245)	(198,720)
Net loss and comprehensive loss	$ (3,825,354)	$ (485,904)	$ (10,327,878)	$ (1,219,767)
Net loss per common share, basic and diluted	$ (0.63)	$ (0.41)	$ (1.71)	$ (1.06)
Weighted-average shares used to compute basic and diluted net loss per share	6,054,250	1,190,212	6,028,309	1,153,751

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Source: Evoke Pharma