Marinus Pharmaceuticals, Inc. Logo

Marinus Pharmaceuticals Provides Business Update and Third Quarter 2018 Financial Results

October 29, 2018

RADNOR, Pa., Oct. 29, 2018 (GLOBE NEWSWIRE) -- Marinus Pharmaceuticals, Inc. (Nasdaq:MRNS) ("Marinus" or "Company"), a biopharmaceutical company dedicated to the development of innovative therapeutics to treat epilepsy and neuropsychiatric disorders, today provided a business update on its clinical development activities and reported its financial results for the third quarter ended September 30, 2018.

"This is an exciting time for Marinus," commented Christopher M. Cashman, chairman and chief executive officer of Marinus. "With enrollment complete in our Magnolia study last quarter, we are on-track to report data shortly. This is our first data readout for ganaxolone in women suffering from postpartum depression, a devastating condition with few treatment options. We will learn how ganaxolone performs in this patient population at various doses and apply these learnings to ongoing and future development as we lay the foundation for later-stage studies."

CDKL5 Deficiency Disorder (CDD)

- The Company is enrolling patients in its pivotal Phase 3 clinical trial (Marigold Study) evaluating the use of oral ganaxolone in children and young adults with CDD. The Marigold Study is a global, double-blind, placebo-controlled, trial that will enroll approximately 70 patients between the ages of 2 and 21 with a confirmed disease-related CDKL5 gene variant. Patients will undergo an 8-week baseline period before being randomized to receive either ganaxolone (up to 1,800 mg/day) or placebo for 17 weeks, in addition to their existing anti-seizure treatment. Following the double-blind treatment period, all patients that meet certain eligibility requirements will have the opportunity to receive ganaxolone in the open label phase of the study. The study's primary efficacy endpoint is percent reduction in seizures. Secondary outcome measures will include non-seizure-related endpoints to capture certain changes in behavior and sleep. There are currently no approved treatments for CDD.

Postpartum Depression (PPD)

- The Company has completed enrollment in the IV only portion of the Magnolia study, a Phase 2 double-blind, placebo-controlled, dose-optimization clinical trial to evaluate ganaxolone in women diagnosed with PPD. The efficacy endpoint is change from baseline in the Hamilton Depression Rating Scale (HAMD17) score. The Company expects to provide top-line data this quarter and announce next steps in our PPD program.

- Enrollment is on-going in the Company's Amaryllis study, a Phase 2 clinical trial to evaluate the safety, tolerability and efficacy of oral ganaxolone in women with PPD. Patients enrolled in the initial open label phase of the study receive one of multiple treatment regimens with oral ganaxolone. The efficacy endpoint is change from baseline in the HAMD17 score. The Company will provide an update on timing for data from the open label phase of the Amaryllis study after release of data from the Magnolia study, as the Magnolia study data may provide dosing insights that inform further oral dose optimization. Upon successful completion of the open label phase, the Amaryllis study is planned to continue as a double-blind placebo-controlled trial.

Status Epilepticus (SE)

- The Company is enrolling patients with refractory status epilepticus (RSE) in its Phase 2 study with ganaxolone IV. Initial data from this proof-of-concept study are expected in the fourth quarter of 2018.

Financial Update

At September 30, 2018, the Company had cash, cash equivalents and investments of $39.6 million. The Company believes that its cash, cash equivalents and investments, as of September 30, 2018, are adequate to fund its operations into 2020.

Research and development expenses increased to $9.1 million and $20.3 million for the three and nine months ended September 30, 2018, respectively, as compared to $2.6 million and $9.0 million for the same periods in the prior year. The increase was related to preclinical and clinical expenses associated with our Phase 2 clinical trials in PPD and RSE and Phase 3 trial in CDD.

General and administrative expenses were $2.1 million and $6.6 million for the three and nine months ended September 30, 2018, respectively, as compared to $1.6 million and $5.1 million for the same periods in the prior year. The increase was driven primarily by an increase in non-cash stock-based compensation expense.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the Securities and Exchange Commission, which includes further detail on the Company's business plans and operations, financial condition and results of operations.

Marinus Pharmaceuticals, Inc.
Selected Financial Data (in thousands, except share and per share amounts)
(unaudited)

	September 30, 2018	December 31, 2017
ASSETS		
Cash and cash equivalents	$19,662	$33,531
Investments	19,967	24,825
Other assets	2,470	2,316
Total assets	$42,099	$60,672
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$6,877	$2,544
Other long term liabilities	100	120
Total liabilities	6,977	2,664
Total stockholders' equity	35,122	58,008
Total liabilities and stockholders' equity	$42,099	$60,672

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expenses				
Research and development	$ 9,148	$ 2,642	$ 20,307	$ 9,032
General and administrative	2,073	1,571	6,599	5,074
Loss from operations	(11,221)	(4,213)	(26,906)	(14,106)
Interest income	111	45	292	116
Interest expense	—	(3)	—	(159)
Other income (expense)	—	1	—	(11)
Net loss	$ (11,110)	$ (4,170)	$ (26,614)	$ (14,160)
Per share information:				
Net loss per share of common stock—basic and diluted	$ (0.27)	$ (0.15)	$ (0.66)	$ (0.60)
Basic and diluted weighted average shares outstanding	40,407,146	28,666,656	40,392,084	23,531,745

About Marinus Pharmaceuticals

Marinus Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to the development of ganaxolone, which offers a new mechanism of action, demonstrated efficacy and safety, and convenient dosing to improve the lives of patients suffering from epilepsy and neuropsychiatric disorders. Ganaxolone is a positive allosteric modulator of $GABA_A$ that acts on a well-characterized target in the brain known to have anti-seizure, anti-depressant and anti-anxiety effects. Ganaxolone is being developed in three different dose forms (IV, capsule and liquid) intended to maximize therapeutic reach to adult and pediatric patient populations in both acute and chronic care settings. Marinus has initiated the first ever pivotal study in children with CDKL5 deficiency disorder, a rare form of epilepsy, and is currently conducting studies in patients with postpartum depression and refractory status epilepticus. For more information visit www.marinuspharma.com. Please follow us on Twitter: @MarinusPharma.

Forward-Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Marinus, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as “may”, “will”, “expect”, “anticipate”, “estimate”, “intend”, “believe”, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements regarding our interpretation of preclinical studies, development plans for our product candidate, including the development of dose forms, the clinical trial testing schedule and milestones, the ability to complete enrollment in our clinical trials, interpretation of scientific basis for ganaxolone use, timing for availability and release of data, the safety, potential efficacy and therapeutic potential of our product candidate and our expectation regarding the sufficiency of our working capital. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the conduct of future clinical trials, the timing of the clinical trials, enrollment in clinical trials, availability of data from ongoing clinical trials, expectations for regulatory approvals, the attainment of clinical trial results that will be supportive of regulatory approvals, and other matters, including the development of formulations of ganaxolone, and the availability or potential availability of alternative products or treatments for conditions targeted by the Company that could affect the availability or commercial potential of our drug candidates. Marinus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see filings Marinus has made with the Securities and Exchange Commission.

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