Marinus Pharmaceuticals Provides Business Update and First Quarter 2018 Financial Results

May 2, 2018

RADNOR, Pa., May 02, 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 first quarter ended March 31, 2018.

Near-term Clinical Value Catalysts (unchanged)

- Initiate Phase 3 Marigold pivotal study with oral ganaxolone in children with CDKL5 deficiency disorder (CDD) mid-2018
- Report top-line intravenous (IV) ganaxolone data from Phase 2 Magnolia study in women with severe postpartum depression (PPD) third quarter 2018
- Report top-line oral ganaxolone data from Amaryllis study in women with moderate PPD fourth quarter 2018

"Our team is laser-focused on enrolling our studies in women with postpartum depression and preparing the medical community for a soon-to-initiate global phase 3 pivotal study in children with CDKL5 deficiency disorder," commented Christopher M. Cashman, chairman and chief executive officer of Marinus. "We expect our PPD studies to generate data this year that will inform our Phase 3 program. We look forward to providing updates on our progress in these areas in the upcoming months."

CDKL5 Deficiency Disorder (CDD)

- The Company expects to begin enrolling CDD patients in its Marigold study in mid-2018. The Marigold study will be a global, double-blind, placebo-controlled, Phase 3 clinical trial in which patients will undergo a baseline period followed by a treatment period. The study's primary efficacy endpoint will be percent reduction in seizures. Further study details will be released once the study has been initiated.

Postpartum Depression (PPD)

- Enrollment is ongoing in the Company's Magnolia study, a Phase 2 double-blind, placebo-controlled, dose-optimization clinical trial to evaluate ganaxolone in women diagnosed with severe PPD (Hamilton Depression Rating Scale (HAMD17) score ?26). The primary efficacy endpoint in the Magnolia study is change from baseline in the HAMD17 score. Patients randomized into the first part of the study will undergo a 60-hour infusion of either ganaxolone or placebo and will be followed for 30 days. The Company expects to complete the IV portion (part one) of the study in the third quarter of 2018. These data will be used to inform dosing for part two of the study, which is planned to evaluate regimens that include both IV and oral formulations of ganaxolone.

- Enrollment is also on-going in the Company's Amaryllis study, a Phase 2 double-blind, placebo-controlled clinical trial to evaluate the safety, tolerability and efficacy of oral ganaxolone in women with moderate PPD (HAMD17 score between 20 and 25). Patients enrolled in the study will receive up to two weeks of treatment with ganaxolone capsules and will be followed for 14 days. The primary efficacy endpoint is change from baseline in the HAMD17 score. Data from this study are expected fourth quarter of 2018.

Status Epilepticus (SE)

- The Company has initiated its Phase 2 study with ganaxolone IV in patients with refractory status epilepticus (RSE). Ganaxolone IV will be added to standard of care and administered for up to five days. The primary endpoint of the study is the number of subjects who do not require IV anesthetic for status epilepticus treatment within the first 24 hours after study drug initiation. Initial data from this proof-of-concept study are expected fourth quarter of 2018.

Financial Update

At March 31, 2018, the Company had cash, cash equivalents and investments of $52.0 million, compared to $58.4 million at December 31, 2017. The Company believes that its cash, cash equivalents and investments, as of March 31, 2018, are adequate to fund its operations into 2020.

Research and development expenses increased to $3.9 million for the three months ended March 31, 2018, as compared to $3.6 million for the same period 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 planned Phase 3 trial in CDD.

General and administrative expenses were $2.2 million for the three months ended March 31, 2018 as compared to $1.8 million for the same period in the prior year. The expense increase was driven primarily by an increase in 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 March 31, 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.

Selected Financial Data (in thousands, except share and per share amounts)
(unaudited)

	March 31, 2018	December 31, 2017
ASSETS		
Cash and cash equivalents	$27,181	$33,531
Investments	24,839	24,825
Other assets	3,013	2,316
Total assets	$55,033	$60,672
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	1,794	2,544
Other long term liabilities	114	120
Total liabilities	1,908	2,664
Total stockholders' equity	53,125	58,008
Total liabilities and stockholders' equity	$55,033	$60,672

	Three Months Ended March 31, 2018	2017
Expenses:		
Research and development	$ 3,927	$ 3,573
General and administrative	2,187	1,812
Loss from operations	(6,114)	(5,385)
Interest income	116	40
Interest expense	—	(84)
Other income (expense)	(1)	(9)
Net loss	$ (5,999)	$ (5,438)
Per share information:		
Net loss per share of common stock—basic and diluted	$ (0.15)	$ (0.26)
Basic and diluted weighted average shares outstanding	40,373,083	20,580,558

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 both anti-seizure 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 is preparing to initiate a pivotal study in children with CDKL5 deficiency disorder, a rare form of epilepsy, and 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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