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Marinus Pharmaceuticals Provides Business Update and Reports Third Quarter 2016 Financial Results

RADNOR, Pa., Nov. 03, 2016 (GLOBE NEWSWIRE) -- [Marinus Pharmaceuticals, Inc.](#) (Nasdaq:MRNS), a biopharmaceutical company dedicated to the development of innovative therapeutics to treat epilepsy and other neuropsychiatric disorders, today provided a business update and announced its financial results for the third quarter ended September 30, 2016.

"We have made significant progress in advancing our status epilepticus program supported by our new intravenous formulation of ganaxolone," commented Christopher M. Cashman, chief executive officer of Marinus Pharmaceuticals. "With the identification of dose levels of ganaxolone IV that we believe to be safe and efficacious, we are preparing to initiate a Phase 2 study in patients suffering from this life-threatening seizure disorder. Additionally, we are expanding the clinical development of ganaxolone into postpartum depression where there is a significant unmet need and a strong mechanistic rationale for a therapeutic benefit from ganaxolone treatment."

Status Epilepticus (SE)

Marinus recently completed its Phase 1 dose-escalation study with ganaxolone IV in 36 healthy subjects. The study was designed to determine the pharmacokinetics, pharmacodynamics, and safety of ganaxolone IV administered as an ascending bolus or continuous infusion dose. Every dose regimen of ganaxolone IV administered, either bolus or continuous infusion, was generally safe and well tolerated. In addition, ganaxolone IV achieved dose levels targeted for efficacy in patients with SE and other indications. Marinus is preparing to commence a Phase 2 clinical trial in patients with SE in the first half of 2017.

PostPartum Depression (PPD)

Marinus plans to initiate a Phase 2 clinical trial in patients with PPD next year. PPD is a mood disorder that affects about 15% of women within the first year of childbirth. Common symptoms include feelings of extreme sadness, hopelessness, suicidal ideation, anxiety, and fatigue. PPD is thought to be linked to the rapid fluctuations in the levels of reproductive hormones and allopregnanolone (allo) after childbirth. Treatment with ganaxolone, which is a one-carbon analog of allo, may provide benefit to women suffering from PPD.

Rare Genetic Seizure and Behavior Disorders in Children

The anxiety and seizure benefits of ganaxolone were recently reported in two phase 2 exploratory studies in children with Fragile X Syndrome and females with PCDH19 genetic epilepsy. Marinus is currently enrolling patients with CDKL5 disorder (CDKL5) and Lennox-Gastaut Syndrome (LGS) in a Phase 2 study and expects data from these additional patient populations in mid-2017.

Upon completion of these additional patients, and based upon the clinical data seen in all the studies conducted in children with rare genetic seizure and behavior disorders, Marinus intends to nominate one or more indications to progress to more advanced clinical studies.

Third Quarter Financial Update

At September 30, 2016, the Company had cash, cash equivalents and investments of \$37.1 million, compared to \$57.7 million at December 31, 2015. The Company believes that its cash, cash equivalents and investments, as of September 30, 2016, are adequate to fund operations into the second half of 2018.

Research and development expenses increased to \$4.8 million and \$17.6 million for the three and nine months ended September 30, 2016, respectively, as compared to \$3.5 million and \$12.9 million for the same periods in the prior year. The increase in the three months ended September 30, 2016 was primarily due to an increase of \$1.3 million associated with preclinical and clinical activities in our IV program. The increase in the nine months ended September 30, 2016 was primarily due to \$1.7 million in clinical manufacturing supplies received, an increase of approximately \$1.9 million in expenses associated with preclinical and clinical activities in our IV program, and approximately \$1.1 million associated with increases in salaries and benefits and noncash stock-based compensation, mostly attributable to increased headcount.

General and administrative expenses increased to \$1.5 million and \$4.7 million for the three and nine months ended September 30, 2016, respectively, as compared to \$1.4 million and \$4.1 million for the same periods in the prior year. The

increase in both periods was primarily due to increases in non-cash stock-based compensation expense.

Marinus reported net losses of \$6.5 million and \$22.6 million for the three and nine months ended September 30, 2016, respectively. Our cash used in operating activities was \$18.7 million for the nine months ended September 30, 2016 compared to \$15.1 million for the same period a year ago.

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, 2016 and Annual Report on Form 10-K 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.

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 CNS-selective GABA_A modulator 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 currently evaluating ganaxolone in orphan pediatric indications for the treatment of genetic seizure and behavior disorders, and preparing to initiate Phase 2 studies in status epilepticus, an orphan indication, and postpartum depression. For more information visit www.marinuspharma.com.

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, and other matters, including the development of formulations of ganaxolone, 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.

Marinus Pharmaceuticals, Inc.

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

	September 30, 2016	December 31, 2015
ASSETS		
Cash and cash equivalents	\$ 32,895	\$ 51,722
Investments	4,171	5,962
Other assets	1,569	1,964
Total assets	<u>\$ 38,635</u>	<u>\$ 59,648</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Total current liabilities	\$ 9,181	\$ 7,435
Notes payable, long-term portion	2,616	5,236
Other long term liabilities	145	56
Total liabilities	<u>11,942</u>	<u>12,727</u>

Total stockholders' equity	26,693	46,921
Total liabilities and stockholders' equity	<u>\$ 38,635</u>	<u>\$ 59,648</u>

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Expenses:				
Research and development	\$ 4,840	\$ 3,472	\$ 17,593	\$ 12,856
General and administrative	1,529	1,378	4,719	4,074
Loss from operations	<u>(6,369)</u>	<u>(4,850)</u>	<u>(22,312)</u>	<u>(16,930)</u>
Interest income	36	15	93	44
Interest expense	(118)	(121)	(365)	(353)
Other income (expense)	(13)	(7)	(44)	2
Net loss	<u>\$ (6,464)</u>	<u>\$ (4,963)</u>	<u>\$ (22,628)</u>	<u>\$ (17,237)</u>
Per share information:				
Net loss per share of common stock—basic and diluted	<u>\$ (0.33)</u>	<u>\$ (0.35)</u>	<u>\$ (1.16)</u>	<u>\$ (1.21)</u>
Basic and diluted weighted average shares outstanding	<u>19,509,220</u>	<u>12,289,939</u>	<u>19,494,424</u>	<u>14,194,793</u>

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