MARINUS PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

Filed 08/01/17 for the Period Ending 08/01/17

Address	170 N RADNOR CHESTER RD SUITE 250 RADNOR, PA 19087
Telephone	484-801-4670
CIK	0001267813
Symbol	MRNS
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report
(Date of earliest event reported)
August 1, 2017

MARINUS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36576**	**20-0198082**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

170 N. Radnor Chester Rd, Suite 250 **Radnor, PA**	**19087**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(484) 801-4670**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 . Results of Operations and Financial Condition .

Marinus Pharmaceuticals, Inc. (the "Company") issued a press release on August 1, 2017 announcing its financial results for the quarter ended June 30, 2017. A copy of the press release is being furnished to the Securities and Exchange Commission as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

The information furnished pursuant to this Item 2.02 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any of the Company's filings with the Securities and Exchange Commission under the Exchange Act or the Securities Act of 1933, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as expressly set forth by specific reference in such a filing. Except as required by law, we undertake no duty or obligation to publicly update or revise the information so furnished.

Item 9.01 . Financial Statements and Exhibits .

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 1, 2017, of Marinus Pharmaceuticals, Inc.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MARINUS PHARMACEUTICALS, INC.

By: /s/ Edward Smith
Edward Smith,
Vice President, Chief Financial Officer,
Secretary and Treasurer

Date: August 1, 2017

EXHIBIT 99.1

MARINUS PHARMACEUTICALS PROVIDES BUSINESS UPDATE AND REPORTS SECOND QUARTER 2017 FINANCIAL RESULTS

Data from Studies in Rare Pediatric Epilepsies and Severe Postpartum Depression Expected in 2nd Half

On-track to Initiate Two Additional Phase 2 Trials Later This Year in Status Epilepticus and Moderate Postpartum Depression

RADNOR, PA, August 1, 2017 (Globe Newswire) -- Marinus Pharmaceuticals, Inc. (Nasdaq:MRNS) (the "Company"), a biopharmaceutical company dedicated to the development of innovative therapeutics to treat epilepsy and neuropsychiatric disorders, today provided a business update and reported its financial results for the quarter ended June 30, 2017.

"This quarter Marinus significantly advanced the development of ganaxolone, which positions us to achieve several value-creating milestones in the second half of this year," said Christopher M. Cashman, Chief Executive Officer of Marinus Pharmaceuticals. "With intravenous dosing occurring in our Magnolia study and plans to initiate the Amaryllis study with ganaxolone capsules, we are well positioned to evaluate inpatient and outpatient treatments with ganaxolone in women diagnosed with both severe and moderate PPD.

We expect to announce top-line data from our Phase 2 trial evaluating children with CDKL5 disorder this quarter. We are interested in ganaxolone's anti-seizure and anti-anxiety activity in improving the quality of life for these children and their families who suffer from seizure and behavioral co-morbidities ."

Second Quarter Clinical Highlights and Updates

- Initiated the Magnolia Study, a phase 2 double-blind, placebo-controlled clinical trial to evaluate the safety, efficacy and pharmacokinetics of intravenous (IV) ganaxolone in women diagnosed with severe PPD. The study consists of multiple cohorts of women with a Hamilton Depression Rating Scale (HAMD17) score $\geq$ 26. Patients randomized to the first study cohort will undergo an infusion of either ganaxolone or placebo and will be followed for at least 30 days. Subsequent cohorts could include shorter- or higher-dose IV regimens alone, or in sequential administration with ganaxolone capsules.

- Received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for ganaxolone for the treatment of CDKL5 disorder. CDKL5 disorder is a severe, rare

genetic disorder with no approved therapies that affects children at an early age and causes difficult-to-control seizures and neuro- developmental impairment.

- Preparations are underway to initiate the Amaryllis Study later this year. This Phase 2 study will evaluate ganaxolone capsules in women with moderate PPD. Ganaxolone capsules have the potential to provide the largest segment of the PPD patient population with access to convenient, oral outpatient therapy. The Company plans to leverage the extensive safety profile associated with ganaxolone capsules to advance the regulatory path of this program. The specific details of the trial design and estimated completion timing will be announced at the time of study initiation.

- Preparations are underway to initiate a Phase 2 study in patients with SE later this year. If SE is not treated immediately, permanent neuronal damage may occur, which contributes to high rates of morbidity and mortality. The Company's approach to address SE is differentiated from other drugs in development. The ganaxolone treatment regimen will target refractory patients with the goal of stopping the seizures earlier and preventing the need for medically-induced coma, which should result in better outcomes for these patients. The specific details of the trial design and estimated completion timing will be announced at the time of study initiation.

Financial Update

At June 30, 2017, the Company had cash, cash equivalents and investment balances of $20.3 million. The Company believes that its cash, cash equivalents and investments, as of June 30, 2017, inclusive of subsequent financing activities, are adequate to fund operations into the fourth quarter of 2018.

Research and development expenses were $2.8 million and $6.4 million for the three and six months ended June 30, 2017, respectively, a decrease of $4.4 million and $6.4 million for the three and six month periods ended June 30, respectively. The decrease was primarily associated with our drug-resistant focal onset seizures program, which discontinued in June 2016, and partially offset by an increase of $0.3 million and $1.0 million for the three and six month periods ended June 30, respectively, associated with our IV programs in PPD and SE.

General and administrative expenses were $1.7 million and $3.5 million for the three and six months ended June 30, 2017, respectively, as compared to similar expense amounts of $1.6 million and $3.2 million for the same periods in the prior year.

Cash used in operating activities $11.2 million for the six months ended June 30, 2017, a decrease of $1.0 million from the same period a year ago. The change in operating activities was driven primarily by a decrease in net loss of $6.2 million, partially offset by a decrease in the change in operating assets and liabilities of $5.2 million.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 to be 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 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 currently evaluating ganaxolone in women with PPD and 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. 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”, “should”,“anticipate”, “estimate”, “intend”, “believe”, “on-track”, 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.

CONTACT:
Lisa M. Caperelli

Executive Director, Investor & Strategic Relations
Marinus Pharmaceuticals, Inc.
484-801-4674
lcaperelli@marinuspharma.com

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

	June 30, 2017	December 31, 2016
ASSETS		
Cash and cash equivalents	$ 19,531	$ 26,178
Investments	744	3,922
Other assets	1,820	1,347
Total assets	$ 22,095	$ 31,447
LIABILITIES AND STOCKHOLDERS' EQUITY		
Total current liabilities	$ 5,674	$ 8,084
Notes payable, long-term portion	—	1,743
Other long term liabilities	132	141
Total liabilities	5,806	9,968
Total stockholders' equity	16,289	21,479
Total liabilities and stockholders' equity	$ 22,095	$ 31,447

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Expenses:				
Research and development	$ 2,817	$ 7,258	$ 6,390	$ 12,752
General and administrative	1,691	1,586	3,503	3,190
Loss from operations	(4,508)	(8,844)	(9,893)	(15,942)
Interest income	31	34	71	56
Interest expense	(72)	(124)	(156)	(248)
Other expense	(3)	(15)	(12)	(31)
Net loss	$ (4,552)	$ (8,949)	$ (9,990)	$ (16,165)
Per share information:				
Net loss per share of common stock—basic and diluted	$ (0.21)	$ (0.46)	$ (0.47)	$ (0.83)
Basic and diluted weighted average shares outstanding	21,985,213	19,509,220	21,288,545	19,486,944