# MARINUS PHARMACEUTICALS INC

## FORM 8-K
(Current report filing)

Filed 05/02/17 for the Period Ending 05/01/17

| | |
|---|---|
| Address | 170 N RADNOR CHESTER RD<br>SUITE 250<br>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)
**May 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**<br>**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:

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. ☐

☐ 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))

Item 2.02 . Results of Operations and Financial Condition .

Marinus Pharmaceuticals, Inc. (the "Company") issued a press release on May 1, 2017 announcing its financial results for the quarter ended March 31, 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 May 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: May 2, 2017

**EXHIBIT 99.1**

**MARINUS PHARMACEUTICALS PROVIDES BUSINESS UPDATE AND REPORTS FIRST QUARTER 2017 FINANCIAL RESULTS**

RADNOR, PA, May 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 March 31, 2017.

**Near-term Clinical Value Catalysts (unchanged)**

- Initiate Phase 2 study in women with postpartum depression (PPD) in 1H 2017
- Report top-line data from children with genetic seizure disorders in mid-2017
- Initiate Phase 2 study in patients with status epilepticus (SE) in 2H 2017

" We have directed our strategy towards indications where we believe there is both a significant unmet medical need and expected therapeutic benefit from ganaxolone's GABA $_A$ modulation mechanism," said Christopher M. Cashman, chief executive officer of Marinus Pharmaceuticals. "With the recent addition of Dr. Lorianne Masuoka as chief medical officer, our clinical leadership is in place to execute on our strategy and vision to improve the lives of patients and their families suffering from seizures, depression and anxiety disorders."

**Recent Publications and Presentations**

- Publication of ganaxolone data in the January issue of *Neuropharmacology* showing reduction in seizures and improvement in behaviors in a preclinical model of Angelman syndrome .
- Platform presentation at the American Academy of Neurology annual meeting of the clinical data from the double-blind, placebo-controlled, cross-over trial evaluating ganaxolone in children and adolescents with Fragile X Syndrome (FXS). Patients enrolled in the study with a higher level of anxiety at baseline showed separation between ganaxolone and placebo in anxiety and positive trends in improvement in attention and hyperactivity.
- Presentation of ganaxolone Phase 1 data at the biannual London-Innsbruck Colloquium on Status Epilepticus and Acute Seizures and selection as a Best Poster for publication in *Epilepsia.* The phase 1 clinical data showed that ganaxolone IV was generally safe, well-tolerated and reached targeted dose levels in a short period of time.

**Financial Update**

At March 31, 2017, the Company had cash, cash equivalents and investments of $24.8 million, compared to $30.1 million at December 31, 2016. The Company believes that its cash, cash equivalents and investments, as of March 31, 2017, are adequate to fund operations into the second half of 2018.

Research and development expenses decreased to $3.6 million for the three months ended March 31, 2017, as compared to $5.5 million for the same period in the prior year. The decrease was primarily due to a decrease of $2.9 million associated with our drug-resistant focal onset seizures program, which discontinued in June 2016. The decrease was partially offset by an increase of $0.7 million associated with our IV programs in PPD and SE.

General and administrative expenses increased to $1.8 million for the three months ended March 31, 2017, as compared to $1.6 million for the same period in the prior year.

Cash used in operating activities increased to $6.8 million for the three months ended March 31, 2017 compared to $6.1 million for the same period in the prior year. The increase was driven primarily by a net increase in the change in operating assets and liabilities of $2.6 million, partially offset by a decrease in net loss of $1.8 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 March 31, 2017 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 antiseizure and antianxiety 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. 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”, “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:

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

| | March 31, 2017 | December 31, 2016 |
|---|---|---|
| **ASSETS** | | |
| Cash and cash equivalents | $ 22,576 | $ 26,178 |
| Investments | 2,184 | 3,922 |
| Other assets | 2,064 | 1,347 |
| Total assets | $ 26,824 | $ 31,447 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Total current liabilities | $ 6,569 | $ 8,084 |
| Notes payable, long-term portion | 870 | 1,743 |
| Other long term liabilities | 137 | 141 |
| Total liabilities | 7,576 | 9,968 |
| Total stockholders' equity | 19,248 | 21,479 |
| Total liabilities and stockholders' equity | $ 26,824 | $ 31,447 |

| | Three Months Ended March 31, | |
|---|---|---|
| | 2017 | 2016 |
| Expenses: | | |
| Research and development | $ 3,573 | $ 5,494 |
| General and administrative | 1,812 | 1,604 |
| Loss from operations | (5,385) | (7,098) |
| Interest income | 40 | 22 |
| Interest expense | (84) | (124) |
| Other expense | (9) | (16) |
| Net loss | $ (5,438) | $ (7,216) |
| Per share information: | | |
| Net loss per share of common stock—basic and diluted | $ (0.26) | $ (0.37) |
| Basic and diluted weighted average shares outstanding | 20,580,558 | 19,464,669 |