

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): March 14, 2019

**MOLECULIN BIOTECH, INC.**

(Exact Name of Registrant as Specified in its Charter)

**DELAWARE**

(State or Other Jurisdiction of Incorporation  
or Organization)

**001-37758**

(Commission File No.)

**47-4671997**

(I.R.S. Employer Identification No.)

**5300 MEMORIAL DRIVE, SUITE 950, HOUSTON TX 77007**

(Address of principal executive offices and zip code)

**(713) 300-5160**

(Registrant's telephone number, including area code)

(Former name or former address, if changed from 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 (*see* General Instruction A.2. below):

- 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.

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**Item 7.01 Regulation FD Disclosure.**

On March 14, 2019, Moleculin Biotech, Inc. (the "Company") issued a press release announcing the first patients have been treated in the Company's second clinical trial to study Annamycin for the treatment of relapsed and refractory adults with acute myeloid leukemia. The Company further reported that the initial treatment of the first patient appeared to be well tolerated. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein. The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed to be "filed" for the purpose of the Securities Exchange Act of 1934, as amended ("Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

**Exhibit No. Description**

[99.1](#) [Press release dated March 14, 2019](#)

**SIGNATURE**

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

**MOLECULIN BIOTECH, INC.**

Date: March 14, 2019

By: /s/ Jonathan P. Foster  
Jonathan P. Foster  
Chief Financial Officer

## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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<a href="#">99.1</a>	<a href="#">Press release dated March 14, 2019</a>
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## **Moleculin Announces First Patients Treated in European Annamycin Clinical Trial**

HOUSTON - March 14, 2019 -Moleculin Biotech, Inc., (Nasdaq: MBRX) ("Moleculin" or the "Company"), a clinical stage pharmaceutical company with a broad portfolio of drug candidates targeting highly resistant tumors, today announced the first patients have been treated in the Company's second clinical trial to study Annamycin for the treatment of relapsed and refractory adults with acute myeloid leukemia. The Company further reported that the initial treatment of the first patient appeared to be well tolerated.

"We are encouraged to see such ready access to qualified patients in Poland," commented Walter Klemp, Moleculin's Chairman and CEO." We consider it a positive indication to have completed the treatment of the first European patient so soon after beginning recruitment. In addition, we have already begun treatment of the second patient. We also believe that the higher starting dosage in the European trial as compared to the US trial may be contributing to a faster rate of recruitment."

### **About Moleculin Biotech, Inc.**

Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the development of a broad portfolio of oncology drug candidates for the treatment of highly resistant tumors. The Company's clinical stage drugs are: Annamycin, a Next Generation Anthracycline, designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML, WP1066, an Immune/Transcription Modulator capable of inhibiting p-STAT3 and other oncogenic transcription factors while also stimulating a natural immune response, targeting brain tumors, pancreatic cancer and AML, and WP1220, an analog to WP1066, for the topical treatment of cutaneous T-cell lymphoma.

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Moleculin Biotech is also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as compounds capable of Metabolism/Glycosylation Inhibition.

For more information about the Company, please visit <http://www.moleculin.com>.

### **Forward-Looking Statements**

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, the ability of Moleculin to successfully recruit sufficient patients to complete this clinical trial and the ability of Annamycin to show safety and efficacy in patients. Although Moleculin Biotech believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Moleculin Biotech has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under Item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC") and updated from time to time in our Form 10-Q filings and in our other public filings with the SEC. Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

### **Contacts**

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