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 7, 2019

MOLECULIN BIOTECH, INC.
(Exact Name of Registrant as Specified in its Charter)

DELAWARE	**001-37758**	**47-4671997**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File No.)	(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-14(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 [X]

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. [X]

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	MBRX	The NASDAQ Stock Market LLC

Item 7.01 Regulation FD Disclosure.

On May 7, 2019, Moleculin Biotech, Inc. (the "Company") issued a press release announcing additional positive interim safety and efficacy data from its ongoing open label, single arm Phase 1/2 study of Annamycin in Poland. 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 May 7, 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: May 7, 2019

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated May 7, 2019

Moleculin

Exhibit 99.1

Moleculin Announces Additional Positive Interim Results in First Cohort of Phase 1/2 Clinical Studies of Annamycin in Acute Myeloid Leukemia in Europe

2 of 3 patients qualify to proceed to a potentially curative bone marrow transplant; trial advances to next higher dose level

HOUSTON, May 7, 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 additional positive interim safety and efficacy data from its ongoing open label, single arm Phase 1/2 study of Annamycin in Poland. After receiving a single starting dose of 120 mg/m2 in the first cohort of the dose escalation phase of the trial, 2 of 3 patients treated responded sufficiently to qualify for a potentially curative bone marrow transplant. The results for all 3 patients were reviewed by the Safety Review Committee, which determined that no drug-related adverse events were observed that would prevent advancing the trial to the next higher dose level of 150 mg/m2. To date in the European trial, one patient experienced grade 2 mucositis (which resolved to grade 1 within 2 days) and no other adverse events related to Annamycin have been reported. No additional patient data have been developed in the Company's parallel US clinical trial, which is currently recruiting its second cohort to be given a dose level of 120 mg/m2 (the US trial started at a lower initial dose of 100 mg/m2).

"The progress in Europe, specifically Poland, continues to be encouraging," commented Walter Klemp, Moleculin's Chairman and CEO. "In just a few months, we have completed the first cohort and we've seen a partial response from 2 out of 3 patients sufficient to qualify them for a potentially curative bone marrow transplant. It's important to remember that these are relapsed or refractory patients for whom the standard of care failed. So, to see this kind of response at the starting dose level in the dose-ranging phase, we believe is quite remarkable. And, although this data is still preliminary and may not be indicative of the ultimate outcome of the trial, the improvement in activity at 120 mg/m2 in Poland as compared with the 100 mg/m2 cohort in the US is consistent with our expectations for Annamycin."

Mr. Klemp continued: "Recognizing that cardiotoxicity is a significant limitation of existing therapies, we are pleased that we continue to see no evidence of cardiotoxicity in any of the patients treated thus far. Specifically, there was no observed reduction in left ventricle ejection fraction, which is the standard metric for acute cardiotoxicity, nor any change in biomarkers that would indicate the potential for long-term cardiovascular impairment. This is an important step in the ongoing clinical study of Annamycin and toward our goal of ultimately demonstrating the drug's safety and effectiveness to support regulatory approval in both the US and European Union."

Dr. Robert Shepard, Moleculin's Chief Medical Officer for Annamycin added: "With the Polish trial now progressing to 150 mg/m2, we expect to see even better results. And, although 150 mg/m2 was the maximum tolerable dose established by the prior developer of Annamycin due to the incidence of mucositis in patients above that dose level, now that the cryotherapy protocol is well understood to

mitigate the potential for dose-limiting mucositis, there is a good opportunity for dose levels to progress even beyond 150 mg/m2, so the potential to help patients is very exciting."

Study Design

The Company is studying Annamycin in both the US and Poland in open label, single arm clinical trials to assess the safety and efficacy of Annamycin for the treatment of adults with relapsed or refractory acute myeloid leukemia. The US and Polish trials have the same study design, consisting of a Phase 1 intended to establish a "Recommended Phase 2 Dose" ("RP2D"), to which the studies will then proceed. The Phase 1 studies provide for escalating doses in cohorts of 3 patients each, with each successive cohort receiving the next higher dose level until "dose limiting toxicities" prevent further increases. Cohort 1 in Poland received a dose of 120 mg/m2, and the results permit moving to 150 mg/m2. Cohort 1 in the US started at 100 mg/m2, and the results support moving to 120 mg/m2, and the Company is now seeking patients for the second cohort in both studies. (Because one patient in US cohort 1 did not complete the evaluation protocol, a fourth patient was added to complete that cohort.) Once the Company establishes an RP2D, the intent is for each trial to advance to a Phase 2 arm planned to assess the safety and efficacy of Annamycin in 21 additional patients.

We plan to report top-line results by cohort in each trial, with each announcement also including an update on the other trial. Top-line results will include reporting of any drug-related adverse events ("AEs") and assessment of cardiotoxicity, including Echo or MUGA scans measuring change in ejection fraction and measuring blood troponin level, which is considered a biomarker for potential long-term cardiovascular impairment. To date, one patient experienced grade 2 mucositis (which resolved to grade 1 within 2 days) and no other drug-related AEs have been reported. Also, no loss of ejection fraction or reduction in Troponin levels has been reported. Top-line results will also include the number of partial responses ("PRs"), complete responses ("CRs") and patients deemed capable of progressing to a potentially curative bone marrow transplant, which we term "bridge to transplant" ("BTs"), each of which is essentially a function of the magnitude of reduction in a patient's bone marrow blasts. For purposes of these clinical trials, a CR means, primarily, that the patient's bone marrow blasts reduced to 5% or less, a PR means the patient's bone marrow blasts reduced, but not to the level of a CR, and a BT means patients are deemed capable of progressing to a potentially curative bone marrow transplant. To date, there have been no PRs, CRs or BTs in the US trial, which has treated 4 patients at 100 mg/m2, and 2 PRs and BTs out of 3 patients treated in the Polish trial at 120 mg/m2.

The US trial also differs from the Polish trial in that the FDA would like to review safety data relating to cardiotoxicity from patients treated prior to advancing beyond 120 mg/m2. The Company believes that the additional patient safety data gained from the Polish trial may also assist in the FDA's review of cardiac safety.

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 hematologic malignancies, and WP1220, an analog to WP1066, for the topical treatment of cutaneous T-cell lymphoma. Moleculin 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 the Company to successfully recruit patients to complete its clinical trials and the ability of Annamycin to show safety and efficacy in patients. Although Moleculin 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. The Company cautions investors not to place undue reliance on the interim results announced today.

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