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): July 18, 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 Symbol (s)**	**Name of each exchange on which registered**
Common Stock, par value $.001 per share	MBRX	The NASDAQ Stock Market LLC

Item 7.01 Regulation FD Disclosure.

On July 18, 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. Three patients were treated at dose level of 150 mg/m^2 with no drug-related adverse events, including no signs of cardiotoxicity.

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 July 18, 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: July 18, 2019

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated July 18, 2019

Moleculin

Exhibit 99.1

Moleculin Announces Annamycin in Acute Myeloid Leukemia in Poland Advances to 3rd Cohort

HOUSTON - July 18, 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. Three patients were treated at dose level of 150 mg/m^2 with no drug-related adverse events, including no signs of cardiotoxicity. The results for all 3 patients were reviewed by the Drug Safety Review Committee, which determined that the trial could progress to the next higher dose level of 180 mg/m^2. To date in Poland, 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. One patient has completed treatment in the 120 mg/m^2 (second) cohort in the Company's parallel US clinical trial (the US trial started at a lower initial dose of 100 mg/m^2).

"Recruitment in Poland continues to move rapidly," commented Walter Klemp, Moleculin's Chairman and CEO. "And, moving beyond the 150 mg/m^2 dosing level is quite significant, as the prior developer of Annamycin was unable to dose beyond this level. We remain optimistic that new methods for reducing the onset of mucositis (the dose limiting toxicity for Annamycin in prior clinical trials) will allow us to safely increase dosing to 180 mg/m^2 or potentially even higher."

Mr. Klemp continued: "It's also important to remind people that one of the advantages we believe Annamycin will offer is a lack of cardiotoxicity. We continue to see no evidence of cardiotoxicity in any of the patients treated thus far. We intend to advance the clinical study of Annamycin with the goal of ultimately demonstrating the drug's safety and effectiveness to support regulatory approval in both the US and European Union."

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. Both the US and Polish trials have the same study design, providing for a Phase 1 intended to establish a "Recommended Phase 2 Dose," ("RP2D") with cohorts of 3 patients each where the first cohort starts at a low beginning dose and each successive cohort receives the next higher dose level until "dose limiting toxicities" prevent further increases. In the case of cohort 1 in the US, one patient did not complete the evaluation protocol, so a fourth patient was added to complete that cohort.

A key difference in the US is that the starting dose was 100 mg/m^2, whereas, in Poland, the starting dose was 120 mg/m^2. Having completed the first cohort in the US, the Company is seeking patients for the second cohort at a dose level of 120 mg/m^2 and 1 of the 3 patients required to fill the cohort has now been treated. Now that 3 patients have completed the safety evaluation period of the second cohort in Poland,

the third cohort will begin there at a dose level of 180 mg/m^2. 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.

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/m^2. The Company believes that the additional patient safety data gained from the Polish trial will 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.

Contacts
Joe Dorame, Robert Blum or Joe Diaz
Lytham Partners, LLC
602-889-9700

mbrx@lythampartners.com