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): February 8, 2021

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 ☒

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. ☒

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 February 8, 2021, Moleculin Biotech, Inc. (the "Company") issued a press release to announce that the Agencja Badañ Medycznych (The Medical Research Agency) a Polish state agency responsible for development of scientific research in the field of medical and health sciences, awarded a grant equivalent to $1.5 million USD to the Maria Sklodowska-Curie National Research Institute to fund a Phase 1B/2 clinical trial of Annamycin for the treatment of soft tissue sarcoma (STS) lung metastases.

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 February 8, 2021
104	Cover page Interactive Data File (embedded within the Inline XBRL document)

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: February 8, 2021

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated February 8, 2021
104	Cover page Interactive Data File (embedded within the Inline XBRL document)

Moleculin Announces Grant Awarded to Polish Research Institute for Independent Clinical Trial of Annamycin in Sarcoma Lung Metastases

HOUSTON, February 8, 2021 /PRNewswire/ -- 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 and viruses, today announced that the Agencja Badañ Medycznych (The Medical Research Agency) a Polish state agency responsible for development of scientific research in the field of medical and health sciences, awarded a grant equivalent to $1.5 million USD to the Maria Sklodowska-Curie National Research Institute to fund a Phase 1B/2 clinical trial of Annamycin for the treatment of soft tissue sarcoma (STS) lung metastases. The grant-funded clinical trial will be led by Prof. Piotr Rutkowski, MD, PhD, Head of Department of Soft Tissue/Bone Sarcoma and Melanoma at the Maria Sklodowska-Curie National Research Institute of Oncology in Warsaw, Poland.

Prof. Piotr Rutkowski will be assisted in part, by WPD Pharmaceuticals in Poland, a licensee of Annamycin, who will provide support in preparation for and conduct of the clinical trial, which is expected to begin this year. As a part of the collaboration between Moleculin and Prof. Rutkowski, Moleculin will be supplying the drug product necessary for the clinical trial, but Moleculin will not participate in conducting the clinical trial. This trial is independent from and will be in addition to the US clinical trial Moleculin is planning to conduct with Annamycin in sarcoma lung metastases.

“There is a significant unmet need for improved treatments for patients with sarcoma lung metastases,” commented Prof. Piotr Rutkowski of Maria Sklodowska-Curie National Research Institute of Oncology, “so we are excited to begin this trial. Although this is considered a rare disease, there are no other clinical trials of this kind currently active in Poland, so it’s a tremendous opportunity for our patients.”

“Prof. Rutkowski’s trial is a key element in a collaboration between teams in the US and Poland,” added Walter Klemp, Chairman and CEO of Moleculin. “We are hopeful that data from the US and Poland can be combined to identify the potential for Annamycin to treat lung metastases.”

Soft tissue sarcomas are the most common form of sarcoma, accounting for an estimated 130,000 incident cases per year worldwide. While many sarcomas can be addressed through surgical removal, it is estimated that as many 20% to 50% of STS sarcomas will eventually metastasize to the lungs, where treatment can become more challenging.

Once metastasized to the lungs, if tumors cannot be surgically removed, the primary chemotherapy regimen is the anthracycline doxorubicin (also known as Adriamycin). While 10% to 30% of patients with sarcoma lung metastases may initially respond to doxorubicin, most will relapse leaving the majority of these patients without an alternative chemotherapy. Treatment options are further limited because of the inherent cardiotoxicity of currently approved anthracyclines, including doxorubicin, which limits the amount of anthracycline that can be given to patients.

Annamycin is a “next generation” anthracycline that has recently been shown in animal models to accumulate in the lungs at up to 34 times the level of doxorubicin. Importantly, Annamycin has also demonstrated a lack of cardiotoxicity in recently conducted human clinical trials for the treatment of acute myeloid leukemia, so the use of Annamycin may not face the same dose limitations imposed on doxorubicin.

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 and viruses. 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 other Immune/Transcription Modulators, as well as WP1122 and related 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 Annamycin to demonstrate safety and efficacy in patients and the ability of the clinical trial to recruit patients on a timely basis. 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 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
James Salierno / Carol Ruth
The Ruth Group
973-255-8361 / 917-859-0214
jsalierno@theruthgroup.com
cruth@theruthgroup.com