

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): December 17, 2020



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-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 December 17, 2020, Moleculin Biotech, Inc. (the "Company") issued a press release announcing that the US Food and Drug Administration (FDA) is allowing the company's Investigational New Drug (IND) application to study Annamycin for the treatment of soft tissue sarcoma lung metastases to go into effect.

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	<a href="#">Press Release dated December 17, 2020</a>
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: December 17, 2020

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

**EXHIBIT INDEX**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
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## **Moleculin Announces FDA Permission to Begin Clinical Study of Annamycin for Sarcoma Lung Metastases**

HOUSTON, December 17, 2020 /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 US Food and Drug Administration (FDA) is allowing the company's Investigational New Drug (IND) application to study Annamycin for the treatment of soft tissue sarcoma lung metastases to go into effect. This allows Moleculin to begin a Phase 1B/2 clinical trial in the US for patients with soft tissue sarcoma that has metastasized to the lungs after first-line therapy for their disease.

It is estimated that there are approximately 36,000 new cases of soft tissue sarcoma (STS) in the 7 major markets (US, EU5 and Japan) each year, and an estimated annual market size of over \$177 million for the treatment of STS lung metastases. Our clinical advisors estimate that approximately half of all STS patients will eventually develop lung metastases from their primary tumor. Although first-line treatments such as surgical resection, chemotherapy and radiation may provide initial therapeutic benefit for an estimated 35% of those patients, there are no approved or emerging second-line therapies for the remaining 65% who relapse or are refractory. Although the lungs tend to be a major site of relapse, we are aware of only 2 active clinical trials specifically targeting STS lung metastases, indicating that Annamycin faces limited competition in this area of development.

Moleculin recently announced that Annamycin demonstrates consistently high antitumor activity in vivo in all tested animal models of different types of lung-localized cancers, including sarcoma. These promising findings correlate with surprisingly high uptake of Annamycin to the lungs in animal models. This uptake is up to 34-fold higher than that of doxorubicin, the primary first-line chemotherapy for STS. The limited pulmonary uptake of doxorubicin in animal models may help explain its lack of activity against STS lung metastases in humans. Additionally, clinical data show no cardiotoxicity associated with the use of Annamycin, as well as the ability to avoid multidrug resistance mechanisms, both of which are often treatment-limiting effects of anthracyclines (which includes doxorubicin) in this setting. Taken together, these factors suggest that Annamycin could represent an important treatment to help address a significant unmet need in patients with STS lung metastases.

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"Since the discovery in animal models of Annamycin's effectiveness in lung metastases, we have been moving quickly to begin a clinical trial in the US to study Annamycin for this indication," commented Walter Klemp, Chairman and CEO of Moleculin. "Recognizing the importance of building on the results with human clinical data, we preemptively included this upcoming trial as part of our budget plan, so our anticipated cash runway into the third quarter of 2021 remains unchanged. We are also collaborating with our partners and physicians in Poland who have shown a high level of interest in testing Annamycin in STS lung metastases and are currently pursuing a possible investigator-led clinical trial in Europe. It is our goal to have to have our US clinical trial begin by mid-2021, with the possibility of also initiating a European investigator-funded clinical trial in 2021."

Mr. Klemp concluded: "Along with the results in STS lung metastases, our animal models have shown significant activity in other lung metastases, including colorectal and triple negative breast cancer, as well as meaningful concentration levels of Annamycin in the liver, spleen and pancreas. Additionally, when tested in a highly aggressive AML mouse model, Annamycin significantly reduced tumor burden in the spleen, lungs and liver, leading to a significant increase in survival. Based on this promising preclinical data, we believe the ultimate market opportunity for Annamycin could be much larger than just STS lung metastases. For all these reasons, we are excited to be moving from the animal models to clinical study."

#### **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>.

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## **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 begin a clinical trial in the US by mid-2021 or the ability of an Investigator-funded trial to begin in Europe during 2021, the ability of Annamycin to demonstrate safety and efficacy in patients, and the Company's estimated cash runway. 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.

## **Contacts**

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