

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 7, 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.)
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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.

Item 8.01. Other Events.

On February 7, 2019, Moleculin Biotech, Inc. (the “Company”) issued a press release announcing approval for its third drug to commence clinical trials. The Company will now have three distinctive oncology drugs in clinic in four ongoing clinical trials. WP1220, a STAT3 inhibitor, is to begin clinical trials in Poland for the treatment of Cutaneous T-Cell Lymphoma ("CTCL"), a rare and deadly skin cancer. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

[99.1](#) [Press release dated February 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: February 7, 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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99.1	Press release dated February 7, 2019
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Moleculin Announces Approval for Third Drug to Commence Clinical Trials

MBRX will now have three distinctive oncology drugs in clinic in four ongoing clinical trials

WP1220, a STAT3 inhibitor, to begin clinical trials in Poland for the treatment of Cutaneous T-Cell Lymphoma ("CTCL"), a rare and deadly skin cancer

HOUSTON - February 7, 2019 -Moleculin Biotech, Inc., (Nasdaq: MBRX) ("Moleculin" or the "Company"), a clinical stage pharmaceutical company focused on the development of oncology drug candidates, all of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center, today announced it has received approval to begin clinical trials in Poland for its STAT3 inhibitor, WP1220, for the topical treatment of Cutaneous T-Cell Lymphoma ("CTCL").

This marks an important milestone for Moleculin. We now have three unique drug candidates in four ongoing clinical trials for the potential treatment of rare and difficult cancers, commented Walter Klemp, Moleculin's Chairman and CEO. We are committed to the strategy of what we call multiple shots on goal, and this latest approval to begin trials means we now have three distinctly different therapies in clinical trials for the potential treatment of rare and difficult cancers.

Dr. Don Picker, Moleculin's Chief Science Officer, added, CTCL is a potentially deadly form of skin cancer involving skin lesions that often have high levels of activated STAT3 (p-STAT3). As a potent inhibitor of p-STAT3, we believe WP1220 may be ideally suited to treat these lesions through topical application, which is what this clinical trial is designed to evaluate.

Dr. Malgorzata Sokolowska-Wojdylo, Dermatology Department Chair at the Medical University of Gdańsk in Poland, and the Principal Investigator running this clinical trial, concluded, There is a significant unmet need for improved topical therapies for CTCL, and we are excited to be the first clinic to evaluate this promising new drug in CTCL patients.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the development of oncology drug candidates, all of which are based on discoveries made at M.D. Anderson Cancer Center. The Company's clinical stage drugs are Annamycin, an 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, and WP1066, an immuno-stimulating STAT3 inhibitor targeting brain tumors, pancreatic cancer and AML. Moleculin Biotech is also engaged in preclinical development of additional drug candidates, including additional STAT3 inhibitors and compounds targeting the metabolism of tumors.

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 that ability of WP1220 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.

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