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 5, 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]

Item 8.01. Other Events.

On February 5, 2019, Moleculin Biotech, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has granted Orphan Drug Status for its drug candidate WP1066 for the treatment of glioblastoma. 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 5, 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 5, 2019

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated February 5, 2019

Moleculin

Exhibit 99.1

Moleculin Announces the FDA has Granted Orphan Drug Designation for its Brain Tumor Drug

HOUSTON - February 5, 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 that the US Food and Drug Administration (FDA) has granted Orphan Drug Status for its drug candidate WP1066 for the treatment of glioblastoma, the most aggressive form of brain tumor.

“We continue to be encouraged by the progress of the physician-led clinical trial of WP1066,” commented Walter Klemp, Moleculin’s Chairman and CEO, “and, now having the FDA grant Orphan Drug status for WP1066 positions us well for potential marketing of this drug. We believe that WP1066 represents a new class of drugs which we call ‘Immune/Transduction Modulators’ because it has demonstrated the ability in preclinical testing in animals to both stimulate a natural immune response to tumors and directly attack tumor cells by inhibiting multiple key oncogenic transcription factors, including STAT3, HIF1-α and c-Myc.”

Dr. Sandra Silberman, Chief Medical Officer for New Projects at Moleculin added: “the development of WP1066 is gaining momentum. In addition to the glioblastoma trial at MD Anderson, we have had interest from additional investigators, including Emory University and Mayo Clinic for conducting clinical trials for the treatment of pediatric brain tumors, as well as others interested in treating a range of highly resistant tumors including AML and pancreatic cancer. Because we’ve seen strong anti-tumor activity in a wide range of animal models, we believe this represents an important new approach to treating many types of cancer.”

The FDA grants orphan drug designation to drugs and biologics that are intended for the treatment of rare diseases that affect fewer than 200,000 people in the U.S. Orphan drug status is intended to facilitate drug development for rare diseases and may provide several benefits to drug developers, including tax credits for qualified clinical trials costs, exemptions from certain FDA application fees, and seven years of market exclusivity upon regulatory product approval.

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 WP1066 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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