

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): August 6, 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.)

**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.  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 August 6, 2019, Moleculin Biotech, Inc. (the "Company") issued a press release announcing that a paper entitled "Immunological Reprogramming in the CNS Tumor Microenvironment and Therapeutic Efficacy of Radiotherapy with STAT3 Blockade" will be presented at the Inaugural Conference on Brain Metastases, in New York City, August 16-17, 2019.

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 August 6, 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: August 6, 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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<u>99.1</u>	<u>Press Release dated August 6, 2019</u>
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## **Moleculin Announces Breakthrough Discovery: WP1066 Potentially Capable of Immune Reprogramming in Glioblastoma Animal Models**

*Data to be presented at the Inaugural Conference on Brain Metastases, August 16-17, 2019*

HOUSTON - August 6, 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 that a paper entitled "Immunological Reprogramming in the CNS Tumor Microenvironment and Therapeutic Efficacy of Radiotherapy with STAT3 Blockade" will be presented at the Inaugural Conference on Brain Metastases, in New York City, August 16-17, 2019.

"As the scientific community is increasingly focused on the potential of STAT3 inhibition for the treatment of cancer, this is a very timely discovery," Walter Klemp, Moleculin's Chairman and CEO, remarked. "Dr. Martina Ott, of MD Anderson Cancer Center, will be presenting the findings of research she conducted in collaboration with Dr. Amy Heimberger (the Principle Investigator of the current investigator-initiated clinical of WP1066 for brain tumors) in combining WP1066 with radiation therapy in glioblastoma animal models. One of the findings of her research that is especially encouraging is that immune-competent mice treated with both radiation and WP1066 developed an immunological memory that enabled them to prevent regrowth of the tumor after these tumor cells were reintroduced. The result was the development of long-term survivors, leading to an increase in overall survival in these models. Of note was that mice with a compromised immune system did not show this effect."

Dr. Sandra Silberman, Moleculin's Chief Medical Officer for New Projects, commented: "Making any kind of impact in treating glioblastoma is exciting, and we think Dr. Heimberger's findings will have a profound impact on understanding the role of STAT3 inhibition, as well as help focus our continued development of WP1066 in this disease. This study was also particularly interesting because it showed the most robust immunological responses were located in the CNS (Central Nervous System) tumor microenvironment rather than peripheral non-tumor tissue. Importantly, the study indicated that the combination of STAT3 inhibition with whole brain radiotherapy had the capacity to enhance the therapeutic effect against established tumors based on immunological competence. We're now very eager to explore this potential in human clinical trials."

### **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,

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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 WP1066 to show safety and efficacy in combination with other treatments in humans. 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 pre-clinical findings announced today.

### **Contacts**

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