

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): September 14, 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, Texas 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 September 14, 2020, Moleculin Biotech, Inc. (the "Company") issued a press release announcing COVID-19 in vivo testing contracted for WP1122.

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 September 14, 2020
104	Cover page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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: September 14, 2020

By: /s/ Jonathan P. Foster

Jonathan P. Foster

Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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Moleculin Announces COVID-19 In Vivo Testing Contracted for WP1122

Additional In Vitro Testing Has Also Begun

HOUSTON, September 14, 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 it has contracted with an independent laboratory to test the antiviral activity of its WP1122 portfolio in a COVID-19 animal model.

Moleculin contracted with an independent laboratory for in vivo testing of its drug candidate, WP1122 and another candidate from the same portfolio in development as a possible treatment for COVID-19. The testing will involve that laboratory's hamster model and SARS-CoV-2. Based on the estimated start date of the study, final data may be available in December.

"With in vivo studies for the treatment of COVID-19 in such high demand, we are excited to begin an in vivo study involving our WP1122 portfolio," commented Walter Klemp, Chairman and CEO of Moleculin. "Even though we may have initial observations earlier, having the final data readout in December will push the estimated window for filing an Investigational New Drug application ("IND") into 2021. We are also planning to conduct other in vivo studies, intended to enable us to file a complete IND with the US Food and Drug Administration ("FDA")."

Based on feedback from FDA, the Company believes it may need to demonstrate activity in a COVID-19 animal model to successfully submit a request for IND status for WP1122. In addition, the Company also continues to contract with independent labs to conduct additional in vitro studies, which are currently under way. "We are excited about the additional in vitro testing as this will involve more than one molecule from our WP1122 anitmetabolite portfolio against SARS-CoV-2 and other viruses," concluded Mr. Klemp.

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, being studied for brain tumors, pancreatic cancer and hematologic malignancies; and WP1220, an analog to WP1066, being studied 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, such as WP1122. Moleculin has the exclusive worldwide rights (subject to certain territories for which it has issued sublicenses) to all of the above technologies.

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 WP1122 to show sufficient antiviral potential in vitro and in vivo models, the ability of Moleculin to file an IND submission and the ability of WP1122 to be shown safe and effective for the treatment of COVID-19, other viral diseases. 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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