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): October 19, 2021

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 ☒

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 October 19, 2021, Moleculin Biotech, Inc. (the "Company"), issued a press release to announce it has received authorization from the Medicines and Healthcare Products Regulatory Agency (MHRA) to commence a Phase 1a clinical trial of WP1122 in the United Kingdom.

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 "filed" for the purpose of the Securities Exchange Act of 1934, as amended ("Exchange Act"), nor shall it be incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended ("Securities Act"), 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 October 19, 2021
104	Cover page Interactive Data File (formatted as 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: October 19, 2021
By: /s/ Jonathan P. Foster
Jonathan P. Foster

Moleculin Receives Authorization from the Medicines and Healthcare Products Regulatory Agency (MHRA) to Commence Phase 1a Clinical Trial of WP1122 for the Treatment of COVID-19

– First-in-human Phase 1a study to evaluate safety and pharmacokinetics of WP1122in healthy volunteers and establish maximum tolerated dose expected to commence in 4th Quarter 2021 –

– Based on previously announced preclinical data demonstrating its antiviral potential, the Company believes WP1122 may potentially help meet the critical need for a pan-viral therapy that could address not only COVID-19 and its variants, but also future viruses –

HOUSTON, October 19, 2021 /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 it has received authorization from the Medicines and Healthcare Products Regulatory Agency (MHRA) to commence a Phase 1a clinical trial of WP1122 in the United Kingdom. WP1122, the Company's lead metabolism/glycosylation inhibitor, is a prodrug of a well-known antimetabolite called 2-deoxy-D-glucose (2-DG) currently being developed for inhibition of viral replication and disease manifestations in humans infected with SARS-CoV-2, the virus responsible for COVID-19. The Company also announced it has received a favorable opinion from the London - Riverside Research Ethics Committee in the UK to begin the study, which is expected to be conducted at the Medicines Evaluation Unit in Manchester, United Kingdom.

"We are incredibly grateful for the ongoing efforts and discussions the MHRA has engaged in with us to advance this important program. Coronaviruses, including SARS-CoV-2, are highly dependent upon glycosylation to form structurally and functionally different essential glycoproteins, as well as glycolysis for energy production. The potent antiviral effect demonstrated by WP1122 in preclinical models to-date is encouraging and bolsters our belief in its potential as an effective therapy for COVID-19," commented Walter Klemp, Chairman and CEO of Moleculin.

The Phase 1a study in healthy human volunteers will investigate the effects of a single ascending dose (SAD) and multiple days of ascending dosing (MAD) of WP1122 administered as an oral solution. Dose escalation will take place in sequential SAD cohorts, and MAD will start as soon as SAD has completed at least 3 dosing cohorts in which WP1122 is found to be safe and well-tolerated. This study in healthy volunteers will explore safety and pharmacokinetics (PK), and subsequent clinical development will be in patients infected with SARS-CoV-2 to further evaluate safety and establish a favorable risk/benefit profile. The Company expects to enroll approximately 80 healthy volunteers in the United Kingdom. The primary endpoint (SAD and MAD) for the study is safety and tolerability, which will be assessed by the frequency of adverse events (AEs), serious adverse events, treatment-emergent adverse events, and AEs of special interest. These will be presented by severity and seriousness, system organ class, preferred term and cohort. Clinically significant changes from baseline in clinical laboratory values, physical examination, vital signs, and electrocardiograms will be documented. The secondary endpoint (SAD and MAD) of the study will be the assessment of PK parameters of WP1122 and its 3 active metabolites. Total duration of study participation for each subject will be up to 4 weeks during SAD and up to 5 weeks during MAD.

WP1122 was developed as a 2-DG prodrug to provide a more favorable pharmacological profile and was found to have greater potency than 2-DG alone in preclinical models where tumor cells require higher glycolytic activity than normal cells. WP1122 has also been shown to have a more potent antiviral effect than 2-DG against SARS-CoV-2 in MRC-5 cells in culture. The improved pharmacokinetic and pharmacodynamic (PK/PD) profile of WP1122 compared to 2-DG was noted in female mice following oral dosing at equimolar (i.e., equivalent levels of 2-DG) doses.

Moleculin Biotech is also in the process of identifying additional countries where potential future Phase 2 COVID-19 clinical studies could occur. The Company is also engaged in preclinical development of additional antimetabolites (WP1096 and WP1097) targeting glycosylation and glycolysis, as well as developing an Investigational New Drug (IND) submission to study WP1122 in cancer patients.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the development of a broad portfolio of drug candidates for the treatment of highly resistant tumors and viruses. The Company's lead program, Annamycin is a next-generation anthracycline designed to be noncardiotoxic and to avoid multidrug resistance mechanisms. In addition, Annamycin has been shown in animal models to reach higher concentration levels than doxorubicin (a leading anthracycline) in certain key organs, such as the lungs, liver and pancreas considered to be difficult-to-reach "sanctuary sites" for tumors. Annamycin is currently in development for the treatment of relapsed or refractory acute myeloid leukemia (AML) and soft tissue sarcoma (STS) lung metastases.

Additionally, the Company is developing 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 and other cancers, and WP1220, an analog to WP1066, for the topical treatment of cutaneous T-cell lymphoma. Moleculin is also engaged in the development of a portfolio of antimetabolites, including WP1122 for the potential treatment of COVID-19 and other viruses, as well as cancer indications including brain tumors, pancreatic and other cancers.

For more information about the Company, please visit www.moleculin.com and connect on Twitter, LinkedIn and Facebook.

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, whether the results of Moleculin's preclinical models can be replicated in human trials, and Moleculin's ability to identify additional countries where potential future Phase 2 COVID-19 clinical studies could occur. 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 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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