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): December 3, 2020

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 December 3, 2020, Moleculin Biotech, Inc. (the "Company") issued a press release to present antitumor activity of annamycin in combination with Ara-C in AML at the American Society for Hematology Annual Conference.

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 December 3, 2020
104	Cover page Interactive Data File (formatted as Inline XBRL)

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: December 3, 2020
By: /s/ Jonathan P. Foster
Jonathan P. Foster
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated December 3, 2020
104	Cover page Interactive Data File (formatted as Inline XBRL)

Moleculin To Present Antitumor Activity of Annamycin in Combination with Ara-C in AML at American Society for Hematology Annual Conference

HOUSTON, December 3, 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 will present animal data demonstrating highly improved activity against acute myeloid leukemia ("AML") in combination with the commonly used antileukemic drug Ara-C (also referred to as "cytarabine") versus single agent at the 62nd Annual Meeting & Exposition of the American Society for Hematology ("ASH") under the title: "High Efficacy of Liposomal Annamycin (L-ANN) in Combination with Cytarabine in Syngeneic p53-null AML Mouse Model."

"We are extremely encouraged by the strong pre-clinical efficacy demonstrated by the combination of Annamycin and Ara-C against AML," commented Walter Klemp, Chairman and CEO of Moleculin. "While we firmly believe in the promise and efficacy Annamycin has demonstrated as a single agent against AML in our two current Phase 1 clinical trials, we believe this discovery warrants further consideration to the potential expansion of its clinical development into clinical trials for the combination of Annamycin with Ara-C ("AnnAraC") against AML."

Mr. Klemp concluded, "The combination of Annamycin with Ara-C is particularly intriguing considering the current first-line therapy for AML patients is "7+3", where Ara-C is administered daily for 7 days in parallel with 3 daily doses of an anthracycline. Substituting a currently used anthracycline such as doxorubicin with Annamycin would be a familiar and well-practiced treatment modality. Furthermore, the combination of Annamycin with Ara-C may offer potential advantages given Annamycin's demonstrated lack of cardiotoxicity and activity against tumor cells resistant to doxorubicin. We look forward to further discussing the promise of this combination at the 62nd Annual Meeting & Exposition of the American Society for Hematology."

As previously announced, the study was conducted in a highly aggressive AML mouse model where median survival, left untreated, is approximately 13 days. Median survival in animals treated with the combination of Annamycin and Ara-C ranged from 56 to 76 days, expanding median survival by 585%. Notably, several animals in the study were completely cured. The Company believes these experiments support initiation for the clinical development of the combination of Annamycin and Ara-C in AML patients.

The study abstract, as accepted by ASH, can be viewed at: https://ash.confex.com/ash/2020/webprogram/Paper143344.html

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, targeting brain tumors, pancreatic cancer and hematologic malignancies, and WP1220, 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 other Immune/Transcription Modulators, as well as WP1122 and related 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 Annamycin to show safety and efficacy in AML patients, alone or in combination with Ara-C and the ability of the Company to receive regulatory authorization to begin a clinical trial for the combination of Annamycin and Ara-C. 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

James Salierno / Carol Ruth
The Ruth Group
973-255-8361 / 917-859-0214
jsalierno@theruthgroup.com
cruth@theruthgroup.com