

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 12, 2021



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 2.02 Results of Operations and Financial Condition.

On August 12, 2021, Moleculin Biotech, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2021 and recent operational highlights. 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.

**ExhibitDescription
No.**

[99.1 Press Release dated August 12, 2021](#)

104 Cover page Interactive Data File (embedded within the 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: August 12, 2021

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



Moleculin Reports Second Quarter 2021 Financial Results and Provides Programs Update

- Continued execution of multiple ongoing clinical studies for the treatment of highly resistant tumors and viruses -

- Key clinical and regulatory milestones throughout next 18 months including topline results from the ongoing Phase 1/2 study of Annamycin for treatment of AML and interim data from U.S. Phase 1b/2 study of Annamycin for the treatment of soft tissue sarcoma (STS) lung metastases -

HOUSTON, August 12, 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 its financial results for the quarter ended June 30, 2021. The Company also provided an update on its portfolio of oncology drug candidates for the treatment of highly resistant tumors and viruses.

"I am pleased with the progress made over the course of the past quarter, of particular note, in the clinical development program for Annamycin, our next-generation anthracycline. We are committed to advancing our three core technologies to meet the needs in a number of oncology and viral indications. We believe the next 18 months hold a number of key inflection points and value drivers for the Company. We believe Moleculin is well-positioned to continue building momentum and drive shareholder value in the near- and long-term," commented Walter Klemp, Chairman and CEO of Moleculin.

Recent Highlights

- Received approval to extend dose escalation in Phase 1/2 European clinical trial evaluating Annamycin for the treatment of acute myeloid leukemia (AML).
- Commenced enrollment and dosed the first subject in its U.S. Phase 1b/2 clinical trial evaluating Annamycin for the treatment of soft tissue sarcoma (STS) lung metastases.
- Held further meetings with the MHRA in the UK regarding a healthy volunteer trial with WP1122 for the treatment of COVID-19.

Programs Update

Next Generation Anthracycline - Annamycin

Annamycin, the Company's next-generation anthracycline was designed to be noncardiotoxic (unlike all currently approved anthracyclines) and has demonstrated its lack of cardiotoxicity in recently conducted human clinical trials for the treatment of AML. The Company believes that, because of this unique improvement in safety, the use of Annamycin may not face the same usage limitations imposed on doxorubicin. Additionally, Annamycin has been shown in animal models to accumulate in the lungs at up to 30-fold the level of doxorubicin. Annamycin is currently in development for the treatment of AML and STS lung metastases. For more information about the Phase 1b/2 study evaluating Annamycin for the treatment of STS lung metastases, please visit clinicaltrials.gov and reference identifier NCT04887298.

Upcoming Milestones Expectations

- H2 2021: Report cohort topline results from the ongoing Phase 1/2 study for treatment of AML and report the study's topline results.
- H2 2021: Commence Phase 1/2 study in Europe for the treatment of AML evaluating combination therapy of Annamycin + AraC.
- H2 2021: Commencement of an investigator-funded, second Phase 1b/2 clinical trial of Annamycin in sarcoma lung metastases in Europe

First-in-class p-STAT3 inhibitors - WP1066 and WP1220

WP1066 is one of several Immune/Transcription Modulators, designed to stimulate the immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs) while also inhibiting key oncogenic transcription factors, including p-STAT3 (phosphorylated signal transducer and activator of transcription 3), c-Myc (a cellular signal transducer named after a homologous avian virus called Myelocytomatosis) and HIF-1 α (hypoxia inducible factor 1 α). These transcription factors are widely sought targets that are believed to contribute to an increase in cell survival and proliferation, and the angiogenesis (coopting vasculature for blood supply), invasion, metastasis and inflammation associated with tumors. They may also play a role in the inability of immune checkpoint inhibitors to affect more resistant tumors. WP1220 is a close analog to WP1066 that the Company has developed as a potential topical therapy for skin-related diseases.

WP1220 was evaluated for the treatment of Cutaneous T-Cell Lymphoma (CTCL) and, based on those results, we are seeking collaborators for future development. WP1066 is currently being evaluated for the treatment of pediatric brain tumors, including Diffuse Interstitial Pontine Glioma (DIPG). Additionally, WP1066 + radiation is being evaluated, pre-clinically, in the treatment of Glioblastoma Multiforme (GBM).

Upcoming Milestones Expectations

- H2 2021: File a US Investigative New Drug application (IND) for the treatment of certain adult cancer(s) with WP1066 and identify an institution to commence an associated investigator-funded Phase 1a/1B study.
- H2 2021: Continue support of the physician-sponsored pediatric brain tumor clinical trial
- H1 2022: Facilitate launch of physician-sponsored Phase 2 study of WP1066 for the treatment of pediatric brain tumors including DIPG.
- Actively seek collaboration with a strategic partner in the near term for external funding for the continued development of WP1220 in a Phase 2 clinical trial as a topical therapy for CTCL.

Infectious Disease and Metabolism/Glycosylation Inhibitors- WP1122, WP1096 and WP1097 Portfolio

Moleculin has new compounds designed to target the roles of glycolysis and glycosylation in both cancer and viral diseases. The Company's lead Metabolism/Glycosylation Inhibitor, WP1122, is a prodrug of 2-DG that appears to improve the drug-like properties of 2-DG by increasing its circulation time and improving tissue/organ distribution. Recent published research has identified that 2-DG has antiviral potential against SARS-CoV-2 *in vitro* and, based on publicly available information, a recently completed Phase 2 clinical trial by an unrelated company in India has reported efficacy in COVID-19 patients, resulting in the Emergency Use Authorization of 2-DG by the Drugs Controller General of India. Moleculin believes WP1122 has the potential to become an important drug to potentiate existing therapies, including checkpoint inhibitors. The Company recently engaged in discussions with the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (UK) regarding the potential for beginning clinical trials of WP1122 without the need for additional preclinical animal efficacy models. Based on their initial discussions with the MHRA, the Company believes that a COVID-19 animal model will not be required in order to submit a clinical trial application (CTA) for a Phase 1 clinical trial beginning with healthy volunteers in that country, although no final determination has been made by the MHRA. During the second quarter these discussions continued. Additionally, the Company is in the process of identifying countries where potential future Phase 2 clinical studies could occur. The Company is also engaged in preclinical development of additional antimetabolites (WP1096 and WP1097) targeting glycolysis and glycosylation.

Upcoming Milestones Expectations

- H2 2021: Seek to initiate Phase 1a/1b study of WP1122 for the treatment of COVID-19 in the UK.
- H2 2021: Potential to launch Phase 2 pivotal study of WP1122 for the treatment of COVID-19 outside the U.S.
- H2 2021: File an IND in the U.S. for the treatment of certain cancers such as GBM and pancreatic cancer, with WP1122.
- Ongoing preclinical development work in anti-viral indications such as HIV, Zika, and Dengue. IND targeted for 2022.

Summary of Financial Results for Second Quarter 2021

Research and development (R&D) expense was \$3.0 million and \$3.3 million for the three months ended June 30, 2021 and 2020, respectively. The decrease of \$0.3 million is mainly related to the timing of costs incurred in 2020 of producing additional drug product for Annamycin clinical trials.

General and administrative expense was \$2.4 million and \$1.7 million for the three months ended June 30, 2021 and 2020, respectively. The increase of \$0.7 million is mainly related to an increase in consulting and advisory fees and an increase in the Company's corporate insurance.

For the six months ended June 30, 2021 and 2020, the Company incurred net losses of \$8.7 million and \$11.3 million, respectively, and had net cash flows used in operating activities of \$10.4 million and \$9.3 million, respectively.

The Company ended the quarter with approximately \$79.5 million of cash. The Company believes that this cash is sufficient to meet its projected operating requirements, which include a forecasted increase over its current R&D rate of expenditures, into 2024.

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, the ability of Moleculin to meet each of the milestones set forth above on the timeline estimated, if at all. 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.

Investor Contact:

JTC Team, LLC
Jenene Thomas
(833) 475-8247
MBRX@jtcir.com

-- Financial Tables Follow--

Moleculin Biotech, Inc.**Unaudited Condensed Consolidated Balance Sheets**

(in thousands)	June 30, 2021	December 31, 2020
Current assets:		
Cash and cash equivalents	\$ 79,506	\$ 15,173
Prepaid expenses and other current assets	2,330	2,025
Total current assets	81,836	17,198
Furniture and equipment, net	395	483
Intangible assets	11,148	11,148
Operating lease right-of-use asset	155	202
Total assets	<u>\$ 93,534</u>	<u>\$ 29,031</u>
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	\$ 3,350	\$ 2,920
Total current liabilities	3,350	2,920
Operating lease liability - long-term, net of current portion	94	159
Warrant liability - long term	5,390	8,192
Total liabilities	8,834	11,271
Total stockholders' equity	84,700	17,760
Total liabilities and stockholders' equity	<u>\$ 93,534</u>	<u>\$ 29,031</u>

Unaudited Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)	Three Months Ended June 30,		Six Months Ended June, 30	
	2021	2020	2021	2020
Revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	3,039	3,329	7,145	6,535
General and administrative and depreciation	2,478	1,705	4,461	3,561
Total operating expenses	5,517	5,034	11,606	10,096
Loss from operations	(5,517)	(5,034)	(11,606)	(10,096)
Other income (loss):				
Gain (loss) from change in fair value of warrant liability	1,173	(5,099)	2,750	(1,254)
Other income, net	8	17	18	22
Interest income, net	92	4	149	7
Net loss	<u>\$ (4,244)</u>	<u>\$ (10,112)</u>	<u>\$ (8,689)</u>	<u>\$ (11,321)</u>
Net loss per common share - basic and diluted	<u>\$ (0.15)</u>	<u>\$ (1.02)</u>	<u>\$ (0.35)</u>	<u>\$ (1.24)</u>
Weighted average common shares outstanding - basic and diluted	<u>28,451,532</u>	<u>9,913,878</u>	<u>25,148,399</u>	<u>9,117,856</u>