

May 12, 2021



Moleculin Reports First Quarter 2021 Financial Results and Provides Programs Update

- Multiple ongoing clinical studies expected to drive key clinical and regulatory milestones throughout next 18 months -

- Significantly strengthened financial position extends cash runway through 2023 -

HOUSTON, May 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 March 31, 2021. The Company also provided an update on its portfolio of oncology drug candidates for the treatment of highly resistant tumors and viruses.



"Over the course of the first quarter, we continued to make significant progress on multiple fronts. Importantly, we have equipped the Company with the resources to advance our portfolio of drug candidates across a number of oncology indications and viruses. On the clinical front, we have the potential to see up to seven clinical trials this year, including investigator sponsored trials. We believe we are well-positioned to execute our strategy and expect to continue to build momentum and drive shareholder value in the near- and long-term," commented Walter Klemp, Chairman and CEO of Moleculin.

Recent Highlights

- Granted Rare Pediatric Disease Designation (RPD) from the U.S. Food and Drug Administration (FDA) to its p-STAT3 inhibitor, WP1066, for the treatment of ependymoma, increasing to a total of four different indications for which a Priority Review Voucher may be granted;
- Engaged IQVIA Biotech to manage Moleculin's effort to begin potential clinical trials of WP1122 for the treatment of COVID-19;
- Received Fast Track Designation from the FDA for its drug, Annamycin, for the treatment of soft tissue sarcoma (STS) lung metastases;

- Announced a \$1.5 million grant was awarded to the Maria Sklodowska-Curie National Research Institute to fund an investigator-initiated Phase 1B/2 clinical trial of Annamycin for the treatment of STS lung metastases;
- Successfully closed a public offering, including full exercise of over-allotment option, for gross proceeds of approximately \$78.0 million, before deducting underwriting discount and offering expenses;
- Announced 100% survival achieved in preclinical study in animals which demonstrated a potentially significant therapeutic benefit of Annamycin against metastatic osteosarcoma; and
- Signed an agreement with Catalyst Clinical Research to manage its U.S. clinical trial to study the ability of Annamycin to treat STS that has metastasized to the lungs.

Programs Update

Next Generation Anthracycline - Annamycin

Annamycin is the Company's "next generation" anthracycline that has recently been shown in animal models to accumulate in the lungs at up to 30-fold the level of doxorubicin (the standard of care chemotherapy for STS lung metastases). Importantly, Annamycin has also demonstrated a lack of cardiotoxicity in recently conducted human clinical trials for the treatment of acute myeloid leukemia (AML), so we believe that the use of Annamycin may not face the same usage limitations imposed on doxorubicin. Annamycin is currently in development for the treatment of AML and STS lung metastases.

Upcoming Milestones

- 2H 2021: Report topline results from ongoing Phase 1/2 study for treatment of AML.
- 2H 2021: Commence Phase 1/2 study in Europe for the treatment of AML evaluating combination therapy of Annamycin + Ara-C.
- 2H 2021: Commence Phase 1b/2 clinical trial of Annamycin for the treatment of STS lung metastases in the U.S.
- 2021: Based on recently announced reimbursement grant awarded in Poland, the Company expects a second Phase 1b/2 clinical trial of Annamycin in sarcoma lung metastases to be primarily investigator-funded 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 is currently being evaluated for the treatment of Cutaneous T-Cell Lymphoma

(CTCL) and WP1066 is currently being evaluated for the treatment of pediatric brain tumors, including Diffuse Interstitial Pontine Glioma (DIPG). Additionally, WP1066 + radiation is being evaluated in the treatment of Glioblastoma Multiforme (GBM).

Upcoming Milestones

- 2H 2021: Facilitate Phase 1/2 study of WP1066 + radiation for the treatment of GBM.
- 1H 2022: Facilitate launch of Phase 2 study of WP1066 for the treatment of pediatric brain tumors, including DIPG.
- Actively seeking 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 that the improved drug-like properties of WP1122 may allow it to outperform 2-DG in COVID-19 patients and may provide the opportunity for it to become an important drug to potentiate existing therapies, including checkpoint inhibitors. Although the Company has seen superior efficacy for WP1122 over 2-DG against SARS-CoV-2 *in vitro*, as well as in multiple animal tumor models, WP1122 has yet to be tested in humans so there can be no assurance that this improved preclinical performance will translate into improved clinical outcomes. The Company is also engaged in preclinical development of additional antimetabolites (WP1096 and WP1097) targeting glycolysis and glycosylation.

Upcoming Milestones

- 2H 2021: Seek to initiate Phase 1a/1b study of WP1122 for the treatment of COVID-19.
- 2H 2021: Potential to launch Phase 2 pivotal study of WP1122 for the treatment of COVID-19.
- 2H 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 First Quarter 2021

Research and development expense was \$4.1 million and \$3.2 million for the three months ended March 31, 2021 and 2020, respectively. The increase of \$0.9 million is mainly related to increased clinical trial activity as described above, increased costs related to sponsored research agreements, and costs related to manufacturing of additional drug product.

General and administrative expense was \$1.9 million and \$1.8 million for the three months ended March 31, 2021 and 2020, respectively. The increase of \$0.1 million is mainly related to an increase in the Company's insurance, which was offset by a similar decrease in travel expenses.

For the three months ended March 31, 2021 and 2020, the Company reported a net loss of \$4.4 million and \$1.2 million, respectively, and had net cash flows used in operating activities of \$ 3.6 million and \$4.3 million, respectively.

The Company ended the quarter with approximately \$86.3 million of cash.

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 timing of the announcement of the results of our clinical trials; our ability to commence new clinical trials for Annamycin for the treatment of AML and STS lung metastases; our ability to commence new clinical trials for WP1066 for the treatment of GBM and DIPG; our ability to commence new clinical trials for WP1122 for the treatment of COVID-19; whether investigator-funded trials will proceed as expected; our ability to find collaboration partners for the continued development of WP1220 for CTCL; our ability to file an IND in the U.S. for the treatment of certain cancers with WP1122; and our ability to file an IND in anti-viral indications such as HIV, Zika, and Dengue. 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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-- Financial Tables Follow--

Moleculin Biotech, Inc.

Unaudited Condensed Consolidated Balance Sheets

(in thousands)	March 31, 2021	December 31, 2020
Current assets:		
Cash and cash equivalents	\$ 86,293	\$ 15,173
Prepaid expenses and other current assets	1,726	2,025
Total current assets	88,019	17,198
Furniture and equipment, net	438	483
Intangible assets	11,148	11,148
Operating lease right-of-use asset	179	202
Total assets	<u>\$ 99,784</u>	<u>\$ 29,031</u>
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	\$ 4,578	\$ 2,920
Total current liabilities	4,578	2,920
Operating lease liability - long-term, net of current portion	127	159
Warrant liability - long term	6,563	8,192
Total liabilities	11,268	11,271
Total stockholders' equity	88,516	17,760
Total liabilities and stockholders' equity	<u>\$ 99,784</u>	<u>\$ 29,031</u>

Unaudited Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)	Three Months Ended March 31,	
	2021	2020
Revenues	\$ —	\$ —
Operating expenses:		
Research and development	4,105	3,206
General and administrative and depreciation	1,983	1,856
Total operating expenses	6,088	5,062
Loss from operations	(6,088)	(5,062)
Other income:		
Gain from change in fair value of warrant liability	1,577	3,845
Other income, net	9	5
Interest income, net	57	3
Net loss	<u>\$ (4,445)</u>	<u>\$ (1,209)</u>
Net loss per common share - basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.15)</u>
Weighted average common shares outstanding - basic and diluted	<u>21,808,565</u>	<u>8,321,833</u>

[releases/moleculin-reports-first-quarter-2021-financial-results-and-provides-programs-update-301289296.html](https://www.molbiotech.com/press-releases/moleculin-reports-first-quarter-2021-financial-results-and-provides-programs-update-301289296.html)

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