November 11, 2021

Moleculin Reports Third Quarter 2021 Financial Results and Provides Programs Update

- Up to six clinical trials expected to be underway or with regulatory clearance by the end of 2021 -

- Preliminary clinical activity for Annamycin seen in interim results from its US Phase 1b/2 clinical trial for the treatment of soft tissue sarcoma (STS) lung metastases -

- STS lung metastases trial continues to recruit rapidly -

- Received favorable opinion from the MHRA to commence first-in-human Phase 1a study to evaluate safety and pharmacokinetics of WP1122 in healthy volunteers for the treatment of COVID-19, expected to commence in Q4 2021 -

- Additional key clinical and regulatory milestones expected throughout the next 18 months -

HOUSTON, Nov. 11, 2021 /PRNewswire/ -- **Moleculin Biotech, Inc.**, (Nasdaq: MBRX) (Moleculin, we or the Company), a clinical stage pharmaceutical company with a broad portfolio of drug candidates targeting highly resistant tumors and viruses, today reported its financial results for the quarter ended September 30, 2021. The Company also provided an update on its portfolio of oncology drug candidates for the treatment of highly resistant tumors and viruses.

"With up to six clinical trials that are either currently underway or expected to have regulatory clearance by the end of 2021, we have made tremendous fundamental progress, and this is truly an exciting time at Moleculin. Furthermore, we believe at least one additional trial will be approved in early 2022. We continue to be encouraged by both the demonstrated potential and data seen across our portfolio of drug candidates," commented Walter Klemp, Chairman

and CEO of Moleculin.

He continued, "We are extremely pleased that the STS lung metastases trial recently expanded to a total of three sites and that we are now in the third cohort with the first patient already treated and the final two patients in screening. This trial continues to recruit rapidly, and, on this pace, we could see the Phase 2 begin in the first half of 2022."

Concluding, he added, "The unmet medical needs that people with highly resistant tumors and viruses are faced with continue to be a driving force as we work to develop safe and effective treatments in a number of oncology and viral indications. We are dedicated to advancing our three core technologies and, I believe, are well-positioned to achieve the key value drivers we expect to see over the next 18 months."

Recent Highlights

- Received authorization from the Medicines and Healthcare Products Regulatory Agency (MHRA) to commence a Phase 1a clinical trial of WP1122 in the United Kingdom 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.

- Reported interim results from its U.S. Phase 1b/2 clinical trial evaluating Annamycin for the treatment of soft tissue sarcoma (STS) lung metastases, which documented preliminary clinical activity for Annamycin.

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 and other currently approved anthracyclines. 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: Report cohort topline results from the ongoing Phase 1/2 study for treatment of STS lung metastases and report the study's topline results.

- H2 2021: Initiate Phase 1/2 study in Europe for the treatment of AML evaluating

combination therapy of Annamycin + Ara-C.

- H1 2022: Commencement of an investigator-funded, second Phase 1b/2 clinical trial of Annamycin in sarcoma lung metastases in Europe.

- H1 2022: Complete Phase 1b portion of ongoing Phase 1b/2 study of Annamycin for the treatment of sarcoma lung metastases in the US.

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-1α (hypoxia inducible factor 1α). 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 Investigational New Drug application (IND) for the treatment of certain adult cancer(s) with WP1066 and begin to identify an institution to commence an associated investigator-funded Phase 1a/1b study.

- H1 2022: Report topline results from Phase 1 physician-sponsored pediatric brain tumor clinical trial.

- H2 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. Based on recently

published research that has identified that 2-DG has antiviral potential against SARS-CoV-2 *in vitro*, Moleculin believes WP1122 has significant potential as a COVID-19 therapy. Its unique mechanism of action may also be well-suited for combinations that potentiate existing therapies, including checkpoint inhibitors.

The Company recently received authorization from the Medicines and Healthcare Products Regulatory Agency (MHRA) to commence a Phase 1a clinical trial of WP1122 in the United Kingdom. The Company also 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. 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.

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 glucose and mannose metabolism.

Upcoming Milestones Expectations

- H2 2021: Commence Phase 1a study of WP1122 for the treatment of COVID-19 in the UK.
- H2 2021: File an IND in the US for the treatment of certain cancers such as GBM and pancreatic cancer with WP1122.
- H1 2022: Potential to launch Phase 2 pivotal study of WP1122 for the treatment of COVID-19 outside of the US.
- Ongoing preclinical development work in anti-viral indications such as HIV, Zika, and Dengue. Collaborations targeted for 2022.

Summary of Financial Results for Third Quarter 2021

Research and development (R&D) expense was $4.1 million and $4.4 million for the three months ended September 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 $2.0 million and $1.7 million for the three months ended September 30, 2021 and 2020, respectively. The increase of $0.3 million is mainly related to an increase in consulting and advisory fees and an increase in our corporate insurance.

For the nine months ended September 30, 2021 and 2020, the Company incurred net losses

of $13.1 million and $14.7 million, respectively, and had net cash flows used in operating activities of $14.7 million and $14.6 million, respectively.

The Company ended the quarter with $75.2 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 visitwww.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 Company' ability to have up to six clinical trials either underway or to have regulatory clearance by the end of 2021, and to have an additional trial approved in early 2022; the Company's ability to meet the clinical trial milestones described in this release; whether the pre-clinical results for WP1122 described are able to be replicated in clinical trials; and the Company's forecasted cash burn rate. 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)	September 30, 2021	December 31, 2020
Current assets:		
Cash and cash equivalents	$ 75,178	$ 15,173
Prepaid expenses and other current assets	1,892	2,025
Total current assets	77,070	17,198
Furniture and equipment, net	353	483
Intangible assets	11,148	11,148
Operating lease right-of-use asset	131	202
Total assets	$ 88,702	$ 29,031
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	$ 3,656	$ 2,920
Total current liabilities	3,656	2,920
Operating lease liability - long-term, net of current portion	75	159
Warrant liability - long term	3,712	8,192
Total liabilities	7,443	11,271
Total stockholders' equity	81,259	17,760
Total liabilities and stockholders' equity	$ 88,702	$ 29,031

Unaudited Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,095	4,435	11,239	10,971
General and administrative and depreciation	2,062	1,716	6,524	5,276
Total operating expenses	6,157	6,151	17,763	16,247
Loss from operations	(6,157)	(6,151)	(17,763)	(16,247)
Other income:				
Gain from change in fair value of warrant liability	1,678	2,743	4,428	1,489
Other income, net	13	10	30	32
Interest income, net	87	3	236	10
Net loss	$ (4,379)	$ (3,395)	$ (13,069)	$ (14,716)
Net loss per common share - basic and diluted	$ (0.15)	$ (0.33)	$ (0.50)	$ (1.55)
Weighted average common shares outstanding - basic and diluted	28,573,476	10,245,810	26,302,638	9,496,585

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