August 12, 2020

Moleculin Biotech, Inc. Reports Financial Results for the Quarter Ended June 30, 2020

HOUSTON, Aug. 12, 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, announced its financial results for the quarter ended June 30, 2020 and provided a business update.

Management Discussion

Walter Klemp, Chairman and CEO of Moleculin, stated, "Despite the difficult backdrop resulting from the global pandemic, we made tremendous progress across all three of our core technologies, particularly in our infectious disease platform of antimetabolites, bolstered our financial position, and added to our experienced leadership team. Importantly, we were pleased to progress our efforts to combat COVID-19, as WP1122, which is often referred to as a "prodrug" of 2-DG and one of our antimetabolites, demonstrated its potential in a number of pre-clinical studies and independent research publications. Independent research found 2-deoxy-D-glucose ("2-DG") reduced replication of SARS-CoV-2, the virus that causes COVID-19, by 100% in in vitro testing. A second independent publication at the University of Campinas in São Paulo further demonstrated the potential of WP1122's mechanism of action as it showed SARS-CoV-2 infection is supported by elevated glucose levels and that inhibition of glycolysis with 2-DG effectively eliminated viral load in vitro. Additionally, two rounds of preclinical testing at one independent lab confirmed by a round of in-vitro testing at a second independent lab in a separate virus host cell line continued to demonstrate WP1122's antiviral activity in SARS-CoV-2. We are very encouraged by this early demonstration of efficacy and are now even more motivated to continue to drive its development. Based on guidance from the FDA, we are pursuing additional studies in animal models, which we believe is the critical path to our expected timing, to further assess WP1122's antiviral capability, with the goal of a possible IND filing in 2020, in preparation for beginning a human clinical trial thereafter."

Mr. Klemp continued, "Although we have expanded the scope and focus of our WP1122 program, our lead candidate, Annamycin, a 'next generation anthracycline' demonstrating little to no cardiotoxicity, still remains one of our key priories. The results from the Phase 1 portion of our US Phase 1/2 clinical trial in acute myeloid leukemia (AML) have been highly

encouraging, as Annamycin met its primary endpoint and demonstrated a clean safety profile with no evidence of cardio-toxicity when delivered to patients at or below the lifetime maximum anthracycline dose established by the FDA. Following these strong results and an independent review of Annamycin, in which the independent expert concluded that he 'does not see evidence of cardio-toxicity', we received authorization from the Polish Department of Registration of Medicinal Products to increase the Phase 1 dose escalation portion of our clinical trial for the treatment of AML. We believe this to be a substantial development in the acceleration of our trial as it allows for the increase in dose escalation increments between cohorts from 30 mg/m^2 to 60 mg/m^2. This will enable our next cohort to increase to 300 mg/m^2, assuming all requirements for safety are met with the 240 mg/m^2 cohort, for which we are currently recruiting. With these dosing expectations, the Company believes that European dosing will increase in 2020, providing for a recommended Phase 2 Dose to be established in 2021. In addition to driving the development of Annamycin, during the second quarter we saw the advancement of WP1066, the lead molecule in Moleculin's portfolio of immune stimulators and modulators of transcription. Importantly, Emory University began recruiting and treating patients in its Phase 1 clinical trial of WP1066 for the treatment of brain tumors in children. We are pleased by the progress of the trial, which has now enrolled and treated three patients. The Emory study, which is being at conducted at the Aflac Cancer & Blood Disorders Center at Children's Healthcare of Atlanta, represents a new approach for treating pediatric brain cancer and benefits from safety data generated in the ongoing clinical trial of WP1066 in adult brain tumors being conducted by MD Anderson Cancer Center."

Mr. Klemp concluded, "With our focus on the continued progression of our candidates and our expansion into infectious disease, we found it prudent to bolster our expertise. As a result, we made several strategic additions to our team at Moleculin. In March, we added Dr. Hongbo Zhai, who has two decades of research and development experience in pharmaceuticals and biotechnology, to our Science Advisory Board. To complement our expanded focus on COVID-19, we then added to our Science Advisory Board Dr. Dominique Schols, a leading virologist at the Rega Institute in Leuven, Belgium, and Dr. Richard Whitley, head of the NIAID Antiviral Drug Discovery and Development Center. With the additions to our team and the progress we made in all three of our programs, we believe we are well positioned to continue to build on the momentum we have achieved thus far in 2020."

Recent Milestones and Accomplishments:

Next Generation Anthracycline - Annamycin

- Announced preclinical data corroborating the efficacy of Annamycin in lung metastases at AACR
- In process with the Polish regulatory authorities' approval to open two additional clinical sites for the Phase 1/2 clinical study
- Approved to accelerate European clinical trial in AML, URPL doubled dose escalation
- Received additional positive safety data in EU AML trial, none of the 19 patients evaluated thus far have shown signs of cardiotoxicity
- Received positive independent report confirming absence of cardiotoxicity (unlike currently approved anthracyclines)
- Announced positive results and successful completion of the Phase 1 portion of the

AML Phase 1/2 trial in the US
- Found to be active against tumor metastases to the lung in pre-clinical testing
- Confirmed anti-tumor efficacy of Annamycin in AML through new animal data
- Expanded drug production to support positive clinical activity
- Received FDA Fast Track designation

Immune/Transcription Modulators - WP1066 Portfolio

- Reported findings that WP1066 used in combination with traditional whole brain radiation therapy (WBRT) resulted in long-term survivors and enhanced median survival time relative to monotherapy in mice with implanted human brain tumors
- Emory University has treated three patients in a Phase 1 clinical trial of WP1066 for the treatment of brain tumors in children after receiving FDA Approval of IND and Emory University Clinical Trial Review Committee approval for STAT3 inhibitor in Investigator Initiated Clinical Trial
- Patent protection filed by MD Anderson covering combination of immune stimulating/transcriptional modulator, including combination with radiation therapy
- Presented preclinical pancreatic cancer data at American Association for Cancer Research Annual Meeting
- Received Orphan Drug Designation from FDA

Infectious Disease and Metabolism/Glycosylation Inhibitors - WP1122 Portfolio

- Independent research team at the University of Campinas in São Paulo, Brazil demonstrated that SARS-CoV-2 infection is supported by elevated glucose levels and that inhibition of glycolysis with 2-DG effectively eliminated viral load in vitro
- Corroborated antiviral activity of WP1122 against coronavirus in pre-clinical testing at IIT Research Institute in another virus host cell line
- Agreement with Sterling Pharma USA LLC for U.S. production of WP1122 to support expanded development efforts
- Two rounds of preclinical assessment of the potential for WP1122 to address COVID-19 at ImQuest BioSciences demonstrated that WP1122 has an antiviral effect on HCoV-229E. The virus yield reduction assay demonstrated a 5 to 10-fold inhibition of coronavirus production by WP1122 when compared to untreated virus control.
- University of Frankfurt found 2-DG to reduce replication of SARS-CoV-2, the virus that causes COVID-19, by 100% in in vitro testing
- Patent filed by MD Anderson covering WP1122 as anti-viral drug candidate
- Final data from Phase 1 proof-of-concept clinical trial for the treatment of cutaneous T-cell lymphoma
- Began preclinical testing of new approach to Pancreatic cancer, opportunity to attack cancer by inhibiting tumor metabolism

Corporate Strategy

- Appointed Dr. Whitley, who leads the Drug Discovery and Development Center for the National Institute of Allergy and Infectious Diseases, to Science Advisory Board
- Added Dr. Dominique Schols, a leading virologist from the Rega Institute to the Moleculin development team as a consultant and a member of our Science Advisory Board
- Appointed Dr. Hongbo Zhai, former Senior Faculty and Supervisor of Postdoctoral

Fellow at University of California San Francisco, to Science Advisory Board

Anticipated 2020 Milestones

- Achieving an MTD or a dose level at or above 300 mg/m^2 in EU AML Phase 1/2 trial for Annamycin
- Expanding our infectious disease portfolio via testing of WP1122 against CoV-2 in animal models and in vitro testing on CoV-2 and other hard to treat viruses with other antimetabolites - resulting in a cancer or virus related IND or its equivalent possibly being filed in 2020
- IND submission for Annamycin for the treatment of tumor metastases to the lung
- Moving WP1220 for the treatment of CTCL forward via a new Phase 2 clinical trial by filing an IND or its equivalent or attempt to join efforts with a strategic partner
- Continued clinical testing in adult and pediatric brain tumors with WP1066 via physician sponsored trials

Financial Results for the Quarter Ended June 30, 2020

Research and development (R&D) expense was $3.3 million and $2.1 million for the three months ended June 30, 2020 and 2019, respectively. The increase of $1.2 million is mainly related to increased clinical trial activity, increased license fees and costs related to sponsored research agreements, costs related to manufacturing of additional drug product and two additional employees in R&D headcount.

General and administrative expense was $1.7 million and $1.5 million for the three months ended June 30, 2020 and 2019, respectively. The increase of $0.2 million was mainly attributable to increased stock-based compensation expense for annual employee stock options and increased costs for directors and officer's liability insurance.

Loss from operations for the second quarter was $5.0 million compared to a net loss of $3.6 million for the second quarter of 2019. This increase was largely due to the above-mentioned increase in R&D.

Net loss for the second quarter of 2020 was $10.1 million, compared to a net loss of $1.2 million in the second quarter of 2019, and was attributed to the above-mentioned increase in R&D and the change in fair value on revaluation of warrant liability associated with warrants issued in conjunction with stock offerings. Changes in our stock price can result in a material gain or loss during the quarter related to the revaluation of our warrant liability. The loss from the change in the fair value of the warrant liability for the second quarter of 2020 was $5.1 million compared to a gain of $2.4 million in the same quarter in 2019. This is a non-cash item.

Liquidity and Capital Resources

As of June 30, 2020, we had cash and cash equivalents of $16.7 million and prepaid expenses and other of $3.0 million. We also had $1.9 million of accounts payable and $1.8 million of accrued expenses. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our clinical trials. For the six months ended June 30, 2020 and 2019, we used approximately $9.3 million and $9.2 million of cash in operating activities, respectively, which represents cash outlays for research and

development and general and administrative expenses in such periods. For the six months ended June 30, 2020 and 2019, net proceeds from financing activities were $15.3 million and $20.8 million, respectively, predominately from the sale of our common stock and the exercise of warrants. Cash used in investing activities for the six months ended June 30, 2020 and 2019 was approximately $0.02 million and $0.03 million, respectively.

We believe that our existing cash and cash equivalents as of June 30, 2020 plus the $1.9 million cash raised subsequent to the quarter will be sufficient to fund our planned operations into the first quarter of 2021, without the issuance of additional equity for cash. Any such issuances should extend the funding of our planned operations beyond the first quarter of 2021. Such plans are subject to our stock price, market conditions, changes in planned expenses depending on clinical enrollment progress, the use of drug product or a combination thereof.

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 visithttp://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 to make an IND submission for WP1122 in 2020; achieving an MTD in the EU AML Phase 1/2 trial for Annamycin in 2021; the ability to make an IND submission for Annamycin for the treatment of tumor metastases to the lung in 2020; moving WP1220 for the treatment of CTCL forward via a new Phase 2 clinical trial by filing an IND or its equivalent or attempt to join efforts with a strategic partner during 2020; and the ability of WP1066 to be shown safe and effective for pediatric brain tumor patients. 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

-- Financial Tables Follow--

Moleculin Biotech, Inc.
Unaudited Condensed Consolidated Balance Sheets

(in thousands)	June 30, 2020	December 31, 2019
Current assets:		
Cash and cash equivalents	$ 16,734	$ 10,735
Prepaid expenses and other current assets	3,015	2,749
Total current assets	19,749	13,484
Furniture and equipment, net	238	316
Intangible assets	11,148	11,148
Operating lease right-of-use asset	245	287
Total assets	$ 31,380	$ 25,235
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	$ 3,739	$ 3,570
Total current liabilities	3,739	3,570
Operating lease liability - long-term, net of current portion	220	276
Warrant liability - long term	11,792	5,818
Total liabilities	15,751	9,664
Total stockholders' equity	15,629	15,571
Total liabilities and stockholders' equity	$ 31,380	$ 25,235

Unaudited Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)	Three Months Ended June 30, 2020	2019	Six Months Ended June, 30 2020	2019
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	3,329	2,099	6,535	5,031
General and administrative and depreciation	1,705	1,533	3,561	3,172
Total operating expenses	5,034	3,632	10,096	8,203
Loss from operations	(5,034)	(3,632)	(10,096)	(8,203)
Other income (loss):				
Gain (loss) from change in fair value of warrant liability	(5,099)	2,407	(1,254)	2,936
Other income, net	17	—	22	—
Interest income, net	4	4	7	5
Net Loss	$ (10,112)	$ (1,221)	$ (11,321)	$ (5,262)
Net loss per common share - basic and diluted	$ (0.17)	$ (0.03)	$ (0.21)	$ (0.15)
Weighted average common shares outstanding - basic and diluted	59,483,267	42,393,031	54,707,132	35,765,790

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