August 16, 2019

Moleculin Biotech, Inc. Reports Financial Results for the Second Quarter Ended June 30, 2019

HOUSTON, Aug. 16, 2019 /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, today announced its financial results for the second quarter ended June 30, 2019. Additionally, the Company announced potential upcoming milestones and recent corporate developments.

Management Discussion

Walter Klemp, chairman and chief executive officer of Moleculin, said, "The second quarter of 2019 exhibited significant progress in the various research initiatives and clinical trials that are underway on our drug candidates. During the quarter, we announced three important research developments that we believe can have meaningful impacts in successfully attacking certain rare and difficult cancers."

"We recently announced an important discovery for the treatment of glioblastoma - one of the most common, and aggressive, types of malignant brain tumor among adults. In animal models, researchers at MD Anderson have combined our lead STAT3 inhibitor - WP1066 - with radiation therapy, the combination of which appears to have developed an immunological memory in immune-competent mice that enabled them to prevent regrowth of the tumor after these tumor cells were reintroduced. The result was the development of long-term survivors, leading to an increase in overall survival in these models. The median survival time with glioblastoma is 15 to 16 months in people who get surgery, chemotherapy, and radiation treatment. This is an important breakthrough that could have a profound impact in extending the lives of people afflicted with glioblastoma in the years to come."

"The second important research development during the quarter," Mr. Klemp continued, "was the announcement of additional positive safety and efficacy data from our ongoing Phase 1/2 study - in Poland - of Annamycin for the treatment of acute myeloid leukemia, and consequently the advancement to our third cohort of patients to be treated. This third cohort of patients will be treated at a dose level of 180 mg/m^2. The previous two cohorts were treated at lower levels - 120 mg/m^2 and 150 mg/m^2, respectively. We believe one of the most

important unique attributes of Annamycin is its lack of cardiotoxicity, since all currently approved anthracyclines are significantly cardiotoxic (potential to damage the heart). Importantly, we have seen no cardiotoxicity in any of the patients treated to date both in the US and in Europe. We believe this is an important pathway that may increase the opportunity for leukemia patients to qualify for potentially life-saving bone marrow transplants at a much higher rate than traditionally has been the case."

"Our third important development during the quarter was the announcement that our ongoing sponsored research at The University of Texas MD Anderson Cancer Center resulted in the discovery that Annamycin, our lead drug candidate for the treatment of acute myeloid leukemia, has demonstrated - in animal models - an ability to significantly improve survival in triple negative breast cancer that has metastasized to the lungs. Annamycin has previously demonstrated a high uptake into the lungs in animal models. Triple-negative breast cancer is considered to be more aggressive and have a poorer prognosis than other types of breast cancer, mainly because there are fewer targeted medicines that treat triple-negative breast cancer. Studies have shown that triple-negative breast cancer is more likely to spread beyond the breast and more likely to recur after treatment. With the demonstrated increased uptake into the lungs in animal models, we are excited about the possibilities for Annamycin in an expanding list of indications."

Mr. Klemp concluded, "From a strategic standpoint, we are highly focused on developing 'multiple shots on goal' for the treatment of rare and difficult cancers. We are pleased with the progress being achieved in our research initiatives and clinical trials. We remain on track to deliver data from our ongoing clinical trials through the balance of the year."

Jonathan Foster, executive vice president and chief financial officer of Moleculin, stated, "From a financial standpoint we are in a strong position. We finished the second quarter with a solid balance sheet with cash of approximately $18.7 million and no debt. The strength of our balance sheet provides us the ability to fund our ongoing research programs and clinical trials. We believe our existing cash and cash equivalents will be sufficient to fund our planned operations well into 2020 without the issuance of additional equity for cash. We are focused on being capital efficient through our important developmental process."

Anticipated Milestones

Anticipated Milestones	Potential Time Frame
Next Generation Anthracycline - Annamycin	
Clinical Trials - Complete cohort of 150 mg/m^2 - prior trial recommended Phase II dose (RP2D)	**Accomplished** and ongoing 2019
Announcement of initial clinical data for Annamycin trial	**Accomplished** and ongoing 2019
Announcement of RP2D for Poland Trial	2020
Poland clinical trial (MB-105) begins Phase II	2020
Approach FDA on U.S. trial (MB-104) on dose expansion using Poland trial data	2020 **(Fast Track Approved)**
Announce additional clinical research in lung and metastatic lung cancers	2020
Immune/Transcription Modulators - WP1066 Family	
Clinical Trials WP 1066 - Announcement of initial clinical data from WP1066 clinician sponsored trial	2019
Phase 1 surgical cohort begins	2020
Transfer clinician sponsored trial WP1066 IND to Moleculin	Second Half of 2019
Emory Physician Led Pediatric Medulloblastoma Trial begins	Second Half of 2019
Announcement of further benefits of our sponsored research agreement with MD Anderson	**Accomplished** and ongoing 2019
Clinical Trial WP1220 - Announce filing and approval of CTA for WP1220 for the treatment of cutaneous T-cell lymphoma (CTCL)	**Accomplished**
Assess WP1220 initial patient data	**Q4-2019**
IND for WP1732 submitted	2020
Dose first patient in Phase I trial for WP1732	2020
Announce further preclinical research results on WP1066 family	**Accomplished** and ongoing 2019
Metabolism/Glycosylation Inhibitors	
Begin preclinical work on WP1122	**Accomplished**
Complete formulation and begin manufacture of drug for trial	First Half of 2020
File IND for WP1122	2020
General Clinical	
Announce a fourth approved clinical trial	**Accomplished**
Announce a fifth approved clinical trial	2019

Second Quarter Highlights and Recent Corporate Developments

Moleculin Announces Breakthrough Discovery: WP1066 Potentially Capable of Immune Reprogramming in Glioblastoma Animal Models - ***Data to be presented at the Inaugural Conference on Brain Metastases, August 16-17, 2019*** - August 6, 2019, the Company announced that a paper entitled "Immunological Reprogramming in the CNS Tumor Microenvironment and Therapeutic Efficacy of Radiotherapy with STAT3 Blockade" will be presented at the Inaugural Conference on Brain Metastases, in New York City, August 16-17, 2019. Dr. Martina Ott, of MD Anderson Cancer Center, will be presenting the findings of the research she conducted in collaboration with Dr. Amy Heimberger (the Principle Investigator of the current investigator-initiated clinical of WP1066 for brain tumors) in combining WP1066 with radiation therapy in glioblastoma animal models.

One of the findings of her research that is especially encouraging is that immune-competent mice treated with both radiation and WP1066 developed an immunological memory that enabled them to prevent regrowth of the tumor after these tumor cells were reintroduced. The result was the development of long-term survivors, leading to an increase in overall survival in these models.

This study was also particularly interesting because it showed the most robust immunological responses were located in the CNS (Central Nervous System) tumor microenvironment rather than peripheral non-tumor tissue. Importantly, the study indicated

that the combination of STAT3 inhibition with whole brain radiotherapy had the capacity to enhance the therapeutic effect against established tumors based on immunological competence.

Moleculin Announces Annamycin in Acute Myeloid Leukemia in Poland Advances to 3rd Cohort - July 18, 2019, the Company announced additional positive interim safety and efficacy data from its ongoing open label, single arm Phase 1/2 study of Annamycin in Poland. Three patients were treated at a dose level of 150 mg/m^2 with no drug-related adverse events, including no signs of cardiotoxicity. The results for all 3 patients were reviewed by the Drug Safety Review Committee, which determined that the trial could progress to the next higher dose level of 180 mg/m^2. To date in Poland, one patient experienced grade 2 mucositis (which resolved to grade 1 within 2 days) and no other adverse events related to Annamycin have been reported. One patient has completed treatment in the 120 mg/m^2 (second) cohort in the Company's parallel US clinical trial (the US trial started at a lower initial dose of 100 mg/m^2). The Company continues to see no evidence of cardiotoxicity in any of the patients treated thus far in its clinical trials.

Moleculin Files for New Patents for Annamycin After Receiving FDA Approval of Fast Track Designation - July 10, 2019, the Company announced it has filed new patents covering the production and reconstitution of Annamycin, which is currently in two clinical trials for the treatment of relapsed or refractory acute myeloid leukemia (AML). Annamycin has Orphan Drug Designation in the US for the treatment of AML and the Company recently announced promising preclinical data showing the potential for Annamycin to become an important treatment for lung metastases. If these patent applications are approved, this will potentially give the Company 20 years of patent protection for Annamycin.

Moleculin Announces Additional Positive Interim Results in First Cohort of Phase 1/2 Clinical Studies of Annamycin in Acute Myeloid Leukemia in Europe - ***2 of 3 patients qualify to proceed to a potentially curative bone marrow transplant; trial advances to next higher dose level*** - May 7, 2019, the Company announced additional positive interim safety and efficacy data from its ongoing open label, single arm Phase 1/2 study of Annamycin in Poland. After receiving a single starting dose of 120 mg/m^2 in the first cohort of the dose escalation phase of the trial, 2 of 3 patients treated responded sufficiently to qualify for a potentially curative bone marrow transplant. The results for all 3 patients were reviewed by the Safety Review Committee, which determined that no drug-related adverse events were observed that would prevent advancing the trial to the next higher dose level of 150 mg/m^2. To date in the European trial, one patient experienced grade 2 mucositis (which resolved to grade 1 within 2 days) and no other adverse events related to Annamycin have been reported. No additional patient data have been developed in the Company's parallel US clinical trial, which is currently recruiting its second cohort to be given a dose level of 120 mg/m^2 (the U.S. trial started at a lower initial dose of 100 mg/m^2).

Moleculin Announces $15.0 Million Registered Direct Offering -April 23,2019, the Company announced that it has entered into definitive agreements with institutional investors to purchase an aggregate of 9,375,000 units at a public offering price of $1.60 per unit in a registered direct offering, which offering was closed on April 25, 2019. Each unit is comprised of one share of common stock and 0.5 of a warrant to purchase one share of common stock. Each warrant has an exercise price of $1.75 per share and is exercisable

immediately. The warrants will expire five years from the date of issuance. The gross proceeds of the offering were approximately $15.0 million, prior to deducting the placement agent fees and other estimated offering expenses.

Moleculin Receives FDA Approval of Fast Track Designation for Annamycin- April 18, 2019, the Company announced that the FDA has approved its request for Fast Track Designation for its drug, Annamycin, for the treatment of relapsed or refractory AML.

A drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers;
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met;
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

Moleculin Announces Significant Discovery in Lung Cancer Models *-Annamycin Found to be Active Against Metastases to the Lungs in Pre-Clinical Testing* - April 17, 2019, the Company announced that its ongoing sponsored research at The University of Texas MD Anderson Cancer Center has now demonstrated that Annamycin is able to significantly improve survival in an aggressive form of triple negative breast cancer metastasized to the lungs in animal models. The Company believes its success in increasing the survival rate in mice with this tumor model in combination with the previously observed high uptake of Annamycin by the lungs is a promising indication that supports additional clinical research in lung and metastatic lung cancers.

Moleculin Announces Agreement with Emory University to Conduct Pediatric Brain Tumor Trial - April 11, 2019, the Company announced it has entered into an agreement with Emory University to conduct a Phase 1 clinical trial of WP1066 in children with recurrent or refractory malignant brain tumors. The study will be conducted at the Aflac Cancer & Blood Disorders Center at Children's Healthcare of Atlanta.

Moleculin Announces Preclinical Pancreatic Cancer Data Presented at American Association for Cancer Research Annual Meeting - April 3, 2019, the Company announced that preclinical data supporting activity of its STAT3-inhibiting Immune/Transcription Modulators was presented by Dr. Waldemar Priebe, Founder and Chair of the Scientific Advisory Board of Moleculin, Inc. at the 2019 Annual Meeting of the American Association for Cancer Research in Atlanta, GA.

AACR Abstract:

https://www.moleculin.com/inhibition-of-stat3-in-pancreatic-ductal-adenocarcinoma-and-immunotherapeutic-implications/

The presentation included data resulting from preclinical evaluation in pancreatic cancer

models of STAT3 inhibitors WP1066 and WP1732, both discovered at The University of Texas MD Anderson Cancer Center and licensed by Moleculin. WP1066 is an orally bioavailable drug with significant brain uptake that is currently in Phase 1 clinical studies in patients with brain tumors. Complementary to WP1066, we believe STAT3 inhibitor WP1732 may be suitable for IV administration and demonstrates high uptake by the pancreas without uptake to the brain.

Financial Results for the Second Quarter ended June 30, 2019

Research and Development Expense. Research and development ("R&D") expense was $2.1 million and $4.2 million for the three months ended June 30, 2019 and 2018, respectively. The decrease of $2.1 million is mainly related to costs incurred in 2018 of producing additional drug product for the Company's Annamycin clinical trials.

General and Administrative Expense. General and administrative expense was $1.5 million and $1.2 million for the three months ended June 30, 2019 and 2018, respectively. The increase of $0.3 million was mainly attributable to an increase in G&A related payroll costs.

Gain from Change in Fair Value of Warrant Liability. We recorded a net gain of $2.4 million in the second quarter of 2019 as compared to a net gain of $0.3 million in the second quarter of 2018, for the change in fair value on revaluation of our warrant liability associated with our warrants issued in conjunction with our stock offerings in April 2019, March 2019, June 2018, February 2018, and February 2017. We are required to revalue certain warrants at the time of each warrant exercise and at the end of each reporting period and reflect in the statement of operations a gain or loss from the change in fair value of the warrant in the period in which the change occurred. We calculated the fair value of the warrants outstanding using the Black-Scholes model. A gain results principally from a decline in our share price during the period and a loss results principally from an increase in our share price. During the quarter, our stock price fluctuated greatly.

Liquidity and Capital Resources

As of June 30, 2019, the Company had cash and cash equivalents of $18.7 million. In April 2019, the Company received gross proceeds of approximately $16.6 million, as a result of a completed public offering and the exercise of various warrants from past public offerings. This brings the Company's total net cash raised through its financing efforts year to date to $20.8 million.

Cash used in operations was $9.2 million for the six months ended June 30, 2019. This $2.9 million increase over the prior year of $6.3 million was mainly due to preparing for clinical trials, an increase in R&D payroll costs, an increase in paid sponsored research and related expenses, and an increase in license fees. These are all a reflection of the ongoing clinical and pre-clinical activity and the associated increase in G&A support for our three core drug technologies.

The Company believes that its existing cash and cash equivalents as of June 30, 2019, will be sufficient to fund planned operations into the second quarter of 2020, without the issuance of additional equity for cash. Such issuances should extend the funding of the Company's planned operations significantly beyond the second quarter of 2020. Such plans

are subject to the Company's 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 treatment of highly resistant cancers. Moleculin has three core technologies, all of which are based on discoveries made at M.D. Anderson Cancer Center by Dr. Waldemar Priebe and his team. The Company's clinical-stage drugs are Annamycin, a Next Generation Anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML, and WP1066, an Immune/Transcription Modulator targeting brain tumors, pancreatic cancer and AML. The Company is also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as Metabolism/Glycosylation Inhibitors. Moleculin's Next Generation Anthracycline, Annamycin, we believe, is unlike any currently approved anthracyclines, as it is designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity. Annamycin has preliminary clinical data suggesting its potential to become the first successful therapy suitable for the majority of relapsed or refractory AML patients and is currently in two Phase I/II clinical trials. WP1066 is one of several Immune/Transcription Modulators capable of stimulating immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs) while also inhibiting key oncogenic transcription factors, including p-STAT3, c-Myc and HIF-1. These transcription factors are widely sought targets that may also play a role in the inability of immune checkpoint inhibitors to affect more resistant tumors. Moleculin is also developing new prodrugs to exploit the potential uses of inhibitors of glycolysis. The Company's lead Metabolism/Glycosylation Inhibitor compound, WP1122, provides an opportunity to cut off the fuel supply of tumors by taking advantage of their overdependence on glucose as compared with healthy cells. New research also points to the potential for the glucose decoy (2-DG) within WP1122 to be capable of enhancing the usefulness of checkpoint inhibitors.

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 of Moleculin to successfully recruit sufficient patients to complete its current clinical trials; the ability of Moleculin to file an IND for WP1732; the ability of Moleculin's drug candidates to show safety and efficacy in patients; and the ability of Moleculin to receive patent protection for Annamycin. Although Moleculin Biotech 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.

---Financial tables on the following page---

Moleculin Biotech, Inc.

Unaudited Condensed Consolidated Balance Sheets (in thousands)	June 30, 2019	December 31, 2018
Current Assets:		
Cash and cash equivalents	$ 18,695	$ 7,134
Prepaid expenses and other	1,507	840
Total current assets	20,202	7,974
Furniture and equipment, net	401	463
Intangible assets	11,148	11,148
Operating lease right-of-use asset	103	—
Total Assets	$ 31,854	$ 19,585
Current Liabilities:		
Accounts payable, accrued expenses and other current liabilities	$ 2,647	$ 3,698
Warrant liability - current	6,944	180
Total current liabilities	9,591	3,878
Operating lease liability - long-term, net of current portion	171	—
Deferred rent - long-term	—	107
Warrant liability - long-term	—	1,328
Total Liabilities	9,762	5,313
Total Stockholders' Equity	22,092	14,272
Total Liabilities and Stockholders' Equity	$ 31,854	$ 19,585

Unaudited Condensed Consolidated Statements of Operations (in thousands, expect shares and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues	$ —	$ —	$ —	$ —
Operating Expenses:				
Research and development	2,099	4,231	5,031	5,469
General and Administrative and depreciation and amortization	1,533	1,227	3,172	2,626
Total operating expenses	3,632	5,458	8,203	8,095
Loss from operations	(3,632)	(5,458)	(8,203)	(8,095)
Other income (expense):				
Gain from change in fair value of warrant liability	2,407	331	2,936	1,040
Other expense	—	(1)	—	(1)
Interest income, net	4	3	5	4
Net loss	$ (1,221)	$ (5,125)	$ (5,262)	$ (7,052)
Loss per common share - basic and diluted	$ (0.03)	$ (0.20)	$ (0.15)	$ (0.29)
Weighted average common shares outstanding - basic and diluted	42,393,031	25,888,931	35,765,790	24,617,372

View original content to download multimedia:http://www.prnewswire.com/news-releases/moleculin-biotech-inc-reports-financial-results-for-the-second-quarter-ended-june-30-2019-300903207.html

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