May 15, 2018

Moleculin Biotech, Inc. Reports Financial Results for the First Quarter Ended March 31, 2018

HOUSTON, May 15, 2018 (GLOBE NEWSWIRE) -- **Moleculin Biotech, Inc.,** (NASDAQ:MBRX) ("Moleculin" or the "Company"), a clinical stage pharmaceutical company focused on the development of oncology drug candidates, all of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center, today announced its financial results for the first quarter ended March 31, 2018. Additionally, the Company announced potential upcoming milestones and recent corporate developments.

Management Discussion

Walter Klemp, Chairman and CEO of Moleculin, said, “The first quarter of 2018 was very productive as we took important steps to advance the clinical trial of our lead compound, Annamycin for the treatment of relapsed or refractory acute amyloid leukemia (“AML”). We entered into an agreement with The University Hospitals Cleveland Medical Center, which includes the Seidman Cancer Center and the Cleveland Clinic, to participate in our U.S. Phase I/II clinical trial of Annamycin to demonstrate safety and efficacy. The first patients were enrolled and treated without incident beginning in late March 2018. We are also awaiting authorization to proceed with our Annamycin clinical trial in Poland, which, if approved by the Polish National Office, would provide a significant and positive expansion of our trial.”

“We are particularly excited with the commencement of the U.S. Annamycin clinical trial because of its unique attributes in treating cancer,” continued Mr. Klemp. “Currently approved drugs for AML are limited in their effectiveness by two key flaws: they are often defeated by something called multidrug resistance, which allows cancer cells to build a resistance to the drug, and at the same time, their dosage is limited by their inherent cardiotoxicity, meaning they can do significant and permanent damage to the heart. Annamycin was uniquely designed to avoid these multiple drug resistance mechanisms and exhibits little to no cardiotoxicity. We believe these unique characteristics could make Annamycin an important new treatment option for AML patients."

“Also, during the quarter, we engaged a contract research organization in anticipation of the expansion of the Annamycin clinical trial in Europe; and we entered into an agreement with a European-based manufacturer to begin preparations for commercial scale production of Annamycin as it moves through the approval process.

We remain highly focused on developing treatments for rare and difficult cancers such as

AML; glioblastoma; cutaneous T-cell lymphoma, (“CTCL), a deadly form of skin cancer; and pancreatic cancer. We have three highly differentiated technologies with breakthrough potential that, we believe, may effectively treat these difficult cancers. From those three core technologies, we now have six potential oncology drug candidates - one of those drugs is currently in clinical trials - with the possibility of two others commencing clinical trial in 2018. We are off to a good start in the first quarter of 2018 and we look forward to building on that momentum throughout the rest of the year.”

First Quarter Highlights and Recent Corporate Developments

Moleculin Announces Engagement with Voisin Consulting Life Sciences to Expand Annamycin Clinical Trial - May 03, 2018, the Company announced that it has engaged Voisin Consulting Life Sciences (“VCLS”), as an additional regulatory consulting firm and contract research organization to prepare for expansion of its clinical trial to study Annamycin for the treatment of relapsed or refractory AML. VCLS headquartered in Paris, France will evaluate Australia and selected Western European countries for the potential expansion of clinical sites for the Company's AML clinical trial.

Moleculin Announces New Data for Immuno-Stimulating Drug to be Presented at International Conference - April 26, 2018, the Company announced that Dr. Waldemar Priebe, Chair of the Company's Scientific Advisory Board, has been selected to present findings on Moleculin's STAT3 inhibitor and immune-stimulating agent, WP1066, at the Global Academic Programs (“GAP”) 2018 in Stockholm, Sweden from May 15 to 17, 2018. The annual GAP Conference provides a forum for faculty from MD Anderson and its Sister Institutions to develop collaborations and exchange research results and ideas. The GAP 2018 Conference is being sponsored by a prestigious list of major pharmaceutical companies, including Roche, Bayer, Bristol-Meyers Squibb, AstraZeneca, Novartis, Merck and Pfizer.

Moleculin Enters Agreement with BSP Pharmaceuticals for its Leukemia Drug Candidate - April 24, 2018, the Company announced that it has entered into an agreement with BSP Pharmaceuticals S.p.A to expand production capability for Annamycin. BSP Pharmaceuticals S.p.A., based in Latina, Italy will begin preparations for commercial scale production of the Annamycin drug product. BSP has a solid track record for supplying liposomal formulations to large pharmaceutical companies.

Moleculin Announces Patients Treated in FDA Approved Phase I/II Annamycin Clinical Trial - April 04, 2018, the Company announced that patients have successfully begun treatment in its U.S. Phase I/II clinical trial of Annamycin for the treatment of relapsed or refractory AML. The first patient enrolled in Moleculin's Annamycin clinical trial was treated at The University Hospitals Cleveland Medical Center Seidman Cancer Center on March 28, 2018.

Moleculin Enters Agreement with Seidman Cancer Center to Conduct Leukemia Clinical Trials Patient -March 27, 2018, the Company announced that it has entered an agreement with The University Hospitals Cleveland Medical Center, which includes the Seidman Cancer Center and the Cleveland Clinic, to participate in its U.S. Phase I/II clinical trial of Annamycin for the treatment of relapsed or refractory AML. Patient enrollment has begun in the Phase I/II trial to demonstrate the safety and effectiveness of

Annamycin in the treatment of AML in a U.S. clinical trial.

Moleculin Announces Grant-Funded Collaboration to Expand Understanding of New Discovery - March 20, 2018, the Company announced it has entered into a collaboration with a team of scientists in Poland who have received a $300,000 research grant to expand the understanding of how Moleculin's leading STAT3 inhibitor WP1066 and the Company's newly discovered drug candidate, WP1732, create a blockade of transcription factor STAT3 leading to tumor cell death and immune-stimulating effects.

Moleculin Announces Pricing of $9 Million Registered Direct Offering - February 16, 2018, the Company announced that it has entered into a definitive agreement with institutional investors for a registered direct offering of securities with gross proceeds of approximately $9 million.

Moleculin Announces Breakthrough Discovery of a New Molecule for Cancer Treatment - February 15, 2018, the Company announced that, pursuant to its continued collaboration with MD Anderson it has developed and licensed what it believes, based on preclinical testing, is a major breakthrough in its effort to develop a new cancer treatment that selectively kills highly resistant tumors. Specifically, the Company has preclinical evidence to suggest it is capable of influencing a process known as 'ubiquitination' to block the activated form of STAT3, an important oncogenic transcription factor. The lead molecule resulting from this new discovery is called WP1732 and it not only appears to share the same key mechanistic properties with WP1066, it has markedly different organ distribution and its dramatically increased solubility makes it ideal for administration via standard IV injection. Importantly, preclinical testing has also shown that WP1732's properties make it a promising candidate for treating pancreatic cancer.

Moleculin Announces Collaboration with Emory University to Develop Novel Treatment of Pediatric Brain Cancer - February 13, 2018, the Company announced it has entered into an agreement with Emory University to enable expanded cancer research on Moleculin's WP1066 molecule for the possible treatment of medulloblastoma, a pediatric malignant primary brain tumor. Physician-scientists at Emory University and Children's Healthcare of Atlanta have requested support to continue research aimed at the development of a novel treatment of medulloblastoma using WP1066 and Moleculin has agreed to supply them with a pure form of WP1066 for preclinical testing for the potential future treatment of patients with the disease. Emory studies so far have indicated that medulloblastoma may be particularly vulnerable to the ability of WP1066 to block the activated form of STAT3, a key signaling protein believed to contribute to the growth and survival of many tumors, including medulloblastoma.

Moleculin Announces Activity with Pancreatic Cancer Drug - February 7, 2018, the Company announced it has been able to show promising tumor suppression activity with its inhibitor of glycolysis, WP1122. The Company’s glycolysis inhibitors have shown a remarkable affinity for concentrating in the pancreas and has solid data showing the ability of WP1122 to inhibit pancreatic tumor growth in mice.

Leading Leukemia Experts Join Moleculin's Science Advisory Board - January 17, 2018, the Company
announced the expansion of its Science Advisory Board to include Drs. Jorge Cortes and

Elihu Estey.

Jorge Cortes, M.D., is deputy chair and professor of medicine in the Department of Leukemia at MD Anderson Cancer Center where he directs the CML and AML Programs. Dr. Cortes received his medical degree in 1986 from the Universidad Nacional Autonoma de Mexico, and has been at MD Anderson since 1991. Dr. Cortes, whose clinical interest focuses on new drug development and the management of patients with myelodysplatic syndromes, acute and chronic leukemias, and myeloproliferative disorders, has authored over 900 peer-reviewed medical publications in top-tier journals including New England Journal of Medicine, Lancet Oncology, Lancet Hematology, Journal of Clinical Oncology, Leukemia, Blood and many others.

Elihu Estey, M.D., is a Professor of Medicine in the Division of Hematology at the University of Washington School of Medicine and a Full Member and Director of AML Clinical Research (non-transplant) Clinical Research Division, Fred Hutchinson Cancer Research Center. Dr. Estey has built a distinguished career in cancer research approaching 40 years of active clinical practice with AML patients, providing mentorships for many physicians that have risen to prominence in AML, lectured globally to professional audiences on cancer research and published more than 700 articles on hematologic malignancies, specifically on AML. Additionally, Dr. Estey serves on the European Leukemia Net (ELN) guidelines committee for AML and has served as an advisor for AML studies to the Oncology Drugs Advisory Committee of the FDA.

Moleculin Expands Leukemia Development Portfolio with Immuno-Stimulating STAT3 Inhibitor - January 10, 2018, the Company announced it has expanded the Company's development pipeline for the treatment of AML with an immuno-stimulating STAT3 inhibitor. Leading experts in the treatment of AML, Dr. Jorge Cortes and Dr. Sanjay Awasthi requested the Company to expand its clinical research to include WP1066, an immuno-stimulating agent and STAT3 inhibitor, to increase therapeutic options for AML patients. This would potentially be complementary and synergistic with Annamycin and existing first line treatments.

Anticipated Milestone	Potential Timeframe
Announcement that our IND for Annamycin has become effective and that we may begin clinical trials	**Accomplished**
Initial IRB (Institutional Review Board) approvals and site initiations of various clinical sites participating in our Phase I/II clinical trial of Annamycin	**Accomplished** and ongoing through Second Half of 2018
Establishment of a new Recommended Phase 2 Dose for Annamycin	Second Half of 2018
A clinician sponsored IND for WP1066 for treatment of adult brain tumors moving forward	**IND Accomplished**; Trial expected to begin First Half of 2018
Announcement of initial clinical data for Annamycin trial	2018
Announcement of further benefits of our sponsored research agreement with MD Anderson	**Accomplished** and Ongoing into 2019
Announce CTA for WP1220 for the treatment of cutaneous T-cell lymphoma (CTCL)	2018

Announce WP1122 and WP1732 move into preclinical work	2018
Announce the fourth drug approved for clinical trial	2019

Financial Results for the First Quarter Ended March 31, 2018

Research and Development Expense. Research and development (R&D) expense was $1.2 million and $0.7 million for the three months ended March 31, 2018 and 2017, respectively. The increase of approximately $0.5 million mainly represents an increase of approximately: $0.2 million related to an increase in R&D associated headcount costs; $0.1 million for sponsored research and related expenses; and, approximately $0.2 million associated with developing and testing drug product as we prepared our IND for Annamycin and for the related clinical trials.

General and Administrative Expense. General and administrative expense was $1.4 million and $0.8 million for the three months ended March 31, 2018 and 2017, respectively. The increase of approximately $0.6 million was mainly attributable to the increase in headcount and associated payroll costs of $0.3 million; $0.1 million of stock-based compensation; and, approximately $0.2 million in other expenses. Such increases are due to the increased corporate activity as the Company enters clinical trials.

Net Loss. The net loss for the three months ended March 31, 2018 was $1.9 million which included non-cash income of $0.2 million related to stock-based compensation and other stock-based expenses.

Liquidity and Capital Resources

As of March 31, 2018, the Company had $13.1 million in cash and cash equivalents. On February 16, 2018, the Company entered into a Securities Purchase Agreement with certain institutional investors for the sale by us of 4,290,000 shares of our common stock, at a purchase price of $2.10 per share. Concurrently with the sale of the common shares, pursuant to the Purchase Agreement, we also sold warrants to purchase 2,145,000 shares of common stock. We sold the common shares and warrants for aggregate gross proceeds of approximately $9.0 million. Subject to certain beneficial ownership limitations, the warrants will be initially exercisable on the six-month anniversary of the issuance date at an exercise price equal to $2.80 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the Purchase Agreement occurred on February 21, 2018. The net proceeds from the transactions was approximately $8.2 million after deducting certain fees due to the placement agent and transaction expenses. The net proceeds will be used for planned clinical trials, preclinical programs, for other research and development activities and for general corporate purposes. The Company believes that its existing cash and cash equivalents as of March 31, 2018 will be sufficient to fund our planned operations into the first quarter of 2019. Such plans are subject to change depending on clinical enrollment progress and use of drug product.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the

development of oncology drug candidates, all of which are based on discoveries made at M.D. Anderson Cancer Center. Our clinical stage drugs are Annamycin, an 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, and WP1066, an immuno-stimulating STAT3 inhibitor targeting brain tumors, pancreatic cancer and AML. We are also engaged in preclinical development of additional drug candidates, including additional STAT3 inhibitors and compounds targeting the metabolism of tumors.

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 potential for Annamycin to demonstrate safety and efficacy in AML patients in clinical trials, the timeframe in which such trials are commenced and completed, and the ability of the Company to obtain Polish regulatory approvals to commence clinical trials for Annamycin in Poland; the willingness and ability of MD Anderson to begin a Phase 1 clinical trial with WP1066, the timeframe in which such trial is completed, and the ability of WP1066 to show safety and efficacy in patients with glioblastoma or melanoma that has metastasized to the brain; the potential for WP1220 to become an effective treatment for CTCL and the ability of the Company to obtain Polish regulatory approvals to commence clinical trials to study WP1220 for CTCL; the ability and timeline pursuant to which the Company is able to prepare the preclinical data necessary for an IND for WP1732; and the potential for WP1122 to become an effective treatment for brain tumors or the ability of a WP1220 analog to become a safe and effective drug for pancreatic cancer in humans. These statements relate to future events, future expectations, plans and prospects. 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.

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

Moleculin Biotech, Inc.
Unaudited Condensed Balance Sheets
(in thousands)

	March 31, 2018	December 31, 2017
Current assets:		
Cash and cash equivalents	$ 13,114	$ 7,714
Prepaid expenses and other	634	588
Total current assets	13,748	8,302
Furniture and equipment, net of accumulated depreciation of $32 and $21, respectively	33	33
Intangible assets	11,148	11,148
Total assets	$ 24,929	$ 19,483
Current liabilities:		
Accounts payable	$ 570	$ 810
Accrued expenses and current liabilities	766	902
Warrant liability	463	503
Total current liabilities	1,799	2,215
Long-term deferred compensation – related party	150	150
Warrant liability - long term	2,410	-
Total liabilities	4,359	2,365
Total Stockholders' Equity	20,570	17,118
Total Liabilities and Stockholders' Equity	$ 24,929	$ 19,483

Moleculin Biotech, Inc.
Unaudited Condensed Statements of Operations
(in thousands except for share and per share amounts)

	Three Months Ended	
	March 31, 2018	December 31, 2017
Revenues	$ -	$ -
Operating Expenses:		
Research and development	1,237	683
General and Administrative and depreciation	1,400	852
Total operating expenses	2,637	1,535

Loss from operations	(2,637)	(1,535)
Other income (expense):		
Gain from change in fair value of warrant liability	709	1,059
Gain from settlement of liability	-	149
Other expense	-	(1)
Interest income (expense), net	1	(1)
Net loss	$ (1,927)	$ (329)
Net loss per common share – basic and diluted	$ (0.08)	$ (0.02)
Weighted average common shares outstanding - basic and diluted	23,331,685	14,590,220

Source: Moleculin Biotech, Inc.