

August 13, 2018



# Moleculin Biotech, Inc. Reports Financial Results for the Second Quarter Ended June 30, 2018

HOUSTON, Aug. 13, 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 MD Anderson Cancer Center, today announced its financial results for the second quarter ended June 30, 2018. Additionally, the Company announced potential upcoming milestones and recent corporate developments.

## Management Discussion

Walter Klemp, Chairman and CEO of Moleculin, said, "During the second quarter, and the first half of 2018, we continued to make measurable progress in achieving important milestones in our three core disruptive technologies and six oncology drug candidates. We are successfully executing our strategic plan to advance our innovative cancer treatment solutions through the regulatory process and work our way toward accelerated FDA approvals by focusing on significant unmet needs. Our recent accomplishments include:

- receiving Polish National Office approval to begin our second Phase I/II clinical trial in Poland to study Annamycin for treatment of relapsed or refractory acute myeloid leukemia ("AML");
- qualified a second and a third U.S. Annamycin clinical site with a fourth, we believe, to come in the near term;
- commencing treatment for the first patient enrolled in the Annamycin U.S. Clinical trial at The University Hospitals Cleveland Medical Center, which includes the Seidman Cancer Center and the Cleveland Clinic;
- announcing the opening of enrollment for a physician-sponsored clinical trial of WP1066 for the treatment of glioblastoma and brain metastases in adults;
- initiating operations in Australia to benefit from potential rebates of up to 43.5% of qualified R&D expenditures and speed up preclinical development;
- commencing preclinical toxicology testing of WP1732, a fully water-soluble STAT3 inhibitor we believe, based on preclinical testing, has the potential to be a breakthrough discovery for rare and difficult to treat cancers through our new subsidiary in Australia; and
- submitting a request to Polish authorities for clinical trial authorization ("CTA") for our STAT3 inhibitor, WP1220, for the treatment of Cutaneous T-Cell Lymphoma ("CTCL") which, if approved, will give us our third drug in clinic.

In our mission to develop breakthrough treatments for rare and difficult cancers, we have developed unique attributes in certain compounds that we believe will: inhibit STAT3 – a prevalent indicator in many cancers; avoid heart damage, eliminate multi-drug resistance with little to no cardiotoxicity; and inhibit metabolic activity by blocking the energy supply cancer cells require and inducing immune system function to target unique and highly metastatic tumors. We believe our three highly differentiated technologies have the potential to effectively attack high profile acute cancer states, ranging from AML; brain tumors; deadly forms of skin cancer; to pancreatic cancer. We currently have two oncology drugs in clinical trials, Annamycin and WP1066, a physician-sponsored trial, with the possibility of two others commencing clinical trials in 2019. This is only possible because of the tireless dedication and the hard work of all our associates at Moleculin. They have driven the momentum that we've achieved to this point while remaining fiscally responsible in our development process. We are highly focused on leveraging our successes to potentially change the treatment for cancer and excited about the opportunities ahead.”

“With total R&D and total operating expense of \$4.2 million and \$5.5 million in the quarter, respectively, it should be noted that we had some one-time R&D charges in the quarter. Specifically, we expensed approximately \$2.3 million related to the production of additional drug product for our Annamycin clinical trials, including product for the expansion beyond the currently planned Phase I/II clinical trial, and the initiation of pre-clinical work on WP1732 in Australia. We believe that the latter will generate Australian income tax credits next calendar year for which cash should be received by our Australian subsidiary in 2019. Furthermore, we incurred \$1 million in R&D expense related to finalizing the acquisition of the license to the non-skin rights of the WP1066 portfolio,” stated Jonathan P. Foster, executive vice president and chief financial officer of Moleculin. He continued, “We expect our R&D expense to be lower going forward on a quarterly basis extending our cash on hand into the second quarter of 2019.”

### Anticipated Milestones

Anticipated Milestone	Potential Timeframe
Announcement that our Investigational New Drug (IND) for Annamycin has become effective and that we may begin clinical trials	<b>Accomplished</b>
Initial IRB (Institutional Review Board) approvals and site initiations of various clinical sites participating in our Phase I/II clinical trial of Annamycin	<b>Accomplished</b> 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	<b>Accomplished</b> ; Now open for enrollment
Announcement of initial clinical data for Annamycin trial	2018
Announcement of further benefits of our sponsored research agreement with MD Anderson	<b>Accomplished</b> and Ongoing into 2019
Announce CTA for WP1220 for the treatment of cutaneous T-cell lymphoma (CTCL)	2018 <b>(CTA Filed)</b>
Announce WP1122 move into preclinical work	2018

Announce WP1732 move into preclinical work	<b>Accomplished</b>
Announce IND for WP1732 submitted	First Half of 2019
Announce a fourth drug approved for clinical trial	2019

## **Second Quarter Highlights and Recent Corporate Developments**

**Moleculin Seeks Approval from Polish Regulatory Agency for Skin Cancer Clinical Trial** - August 9, 2018, the Company announced its submission of a request to Polish authorities for a CTA for its STAT3 inhibitor, WP1220, for the treatment of CTCL which, if approved, will give the Company its third drug in clinic. Published research supports the belief that Cutaneous T-Cell Lymphoma, a deadly form of skin cancer, may be highly dependent on the upregulation of the activated form of STAT3. The Company believes WP1220 may be ideally suited as a topical agent to inhibit STAT3 and therefore could potentially become a valuable new drug for the treatment of CTCL. A request for CTA in Poland is the equivalent of a request for Investigational New Drug status in the U.S.

**Moleculin Announces Enrollment Opens for Brain Tumor Trial of WP1066** - July 31, 2018, the Company announced enrollment opened for a physician-sponsored clinical trial of WP1066 for the treatment of glioblastoma and brain metastases in adults. This is the first investigator-initiated trial of WP1066, an important milestone. The goal of this clinical research study is to find the highest tolerable dose of WP1066 that can be given to patients with recurrent (has returned after treatment) cancerous brain tumors or melanoma that has spread to the brain. The safety of this drug will also be studied. WP1066 is designed to target the STAT3 pathway in cancer cells, which independent research has shown allows these cells to survive and proliferate, increases new blood vessels to the tumor, causes the cancer cells to move throughout the body and brain, and reduces the ability of the immune system to effectively combat tumor development. In addition, the Company believes that WP1066 may also have the potential to stimulate a natural anti-tumor immune response.

**Moleculin Expects to Meet FDA IND Filing Requirements for its Pancreatic Cancer Drug Candidate with Development Work in Australia** - July 18, 2018, the Company announced it began preclinical toxicology testing of its WP1732, a fully water-soluble STAT3 inhibitor with the potential to be a breakthrough discovery for rare and difficult to treat cancers through its new subsidiary in Australia. By utilizing its subsidiary in Australia and the attractive R&D tax credits it offers, it can accelerate the preclinical work of WP1732 and maintain a strong cash balance. The Company believes this will allow it to complete its IND-enabling work and meet FDA submission requirements before year-end, which should allow it to complete the IND filing during 2019, while also reducing the Company's total cost of development.

**Moleculin Expands Operations to Australia; Taps R&D Incentive Program Capped at \$20,000,000 AUD Turnover** - July 11, 2018, the Company announced it had formed Moleculin Australia Pty. Ltd., a wholly-owned subsidiary to oversee preclinical development in Australia. For companies like Moleculin with less than \$20,000,000 AUD group turnover, it can amount to a rebate of up to 43.5% of qualified R&D expenditures. The Australian subsidiary provides a great opportunity to speed up preclinical development and reduce the overall cost of continued drug development efforts.

**Moleculin Selected for the Russell Microcap Index**- June 26, 2018, the Company announced it was selected to be added to the Russell Microcap® Index effective after the U.S. market opened on June 25, 2018, when the Russell Investments reconstituted its comprehensive set of U.S. and global equity indexes. Membership in the Russell Microcap® Index, which remains in place for one year, means automatic inclusion in the appropriate growth and value style indexes.

**Moleculin Announces \$2.3 Million Registered Direct Offering Priced At-the-Market**- June 21, 2018, the Company announced that it entered into a definitive agreement with institutional investors for a registered direct offering of securities with gross proceeds of approximately \$2.3 million, which was completed on June 22, 2018.

**Moleculin Receives Approval for Leukemia Clinical Trial**- June 20, 2018, the Company announced it received Polish National Office approval to begin its second Phase I/II clinical trial to study Annamycin for the treatment of relapsed or refractory AML. Consent from the Polish National Office was the final step required to allow recruitment of patients for this important trial.

**Moleculin Targets accelerated FDA approval of WP1732; Pursues Development for Ocular Tumors** - June 12, 2018, the Company announced that it entered into an agreement with the Jagiellonian University in Krakow, Poland, for the development of its STAT3 inhibitor, WP1732, for the treatment of ocular tumors. The Company believes the water-soluble nature of WP1732 could make it an ideal candidate for targeting these unique and highly metastatic tumors.

**Moleculin's Breakthrough Discovery of a New Molecule for Cancer Treatment Advances to Development Agreement with the University of Iowa** - June 06, 2018, the Company announced that it entered into an agreement with The University of Iowa Pharmaceuticals for the development of a formulation for WP1732. The Company believes WP1732 represents a major expansion of its STAT3 inhibition capability by providing a highly soluble alternative that is ideally suited for IV administration. This agreement marks the beginning of creating a preclinical package to submit to the FDA in order to request Investigational New Drug status.

**Moleculin Invited to Present to International BioForum 2018 Conference**- May 24, 2018, the Company announced that its CEO, Walter Klemp, was asked to address the 2018 BioForum Conference in Łódź, Poland regarding the Polish-American Innovation Bridge: Bringing validated innovations from USA to Poland.

**Moleculin to Begin Clinical Trials at UMC Southwest Cancer Center**- May 16, 2018, the Company announced that a second U.S. site, located in Lubbock, Texas, has qualified for its clinical trial to study Annamycin for the treatment of relapsed or refractory AML. UMC Southwest Cancer Center qualified as the second U.S. site for Moleculin's clinical trial of Annamycin. Dr. Sanjay Awasthi, Division Chief of Hematology/Oncology at Texas Tech University will serve as the site's Principal Investigator.

**Moleculin Announces Engagement with Voisin Consulting Life Sciences to Expand Annamycin Clinical Trial** - May 03, 2018, the Company announced 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 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 it entered into an agreement with BSP Pharmaceuticals S.p.A to expand production capacity 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.

## **Financial Results for the Second Quarter Ended June 30, 2018**

**Research and Development Expense.** Research and development ("R&D") expense was \$4.2 million and \$0.5 million for the three months ended June 30, 2018 and 2017, respectively. The increase of approximately \$3.7 million mainly represents an increase of approximately: \$2.3 million associated with producing additional drug product for the Company's Annamycin clinical trials and with pre-clinical work on WP1732 in anticipation of filing an IND in 2019, \$1.0 million accrued expense related to the HPI Option Repurchase Payment, \$0.2 million related to an increase in R&D associated headcount costs; and \$0.2 million related to various other expenses.

**General and Administrative Expense.** General and administrative expense was \$1.2 million and \$0.8 million for the three months ended June 30, 2018 and 2017, respectively. The increase of approximately \$0.4 million was mainly attributable to the increase in headcount and associated payroll costs of \$0.3 million, and \$0.1 million of stock-based compensation. Such increases are due to the increased corporate activity as the Company enters clinical trials and increases its pre-clinical work on WP1732.

**Net Loss.** The net loss for the three months ended June 30, 2018 was \$5.1 million, which

included non-cash income of \$0.3 million on the gain in fair value of the Company's warrant liability, which was offset by noncash charges for \$0.3 million related to stock-based compensation and other stock-based expenses.

## **Liquidity and Capital Resources**

As of June 30, 2018, the Company had \$11.7 million in cash and cash equivalents. On June 22, 2018, the Company completed the sale to institutional investors for a registered direct offering of securities for the sale of 1,092,636 shares of the Company's common stock, at a purchase price of \$2.105 per share. Concurrently with the sale of the common shares, the Company also sold warrants to the investors 710,212 shares of common stock. The Company sold the common shares and warrants for aggregate gross proceeds of approximately \$2.3 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 \$2.02 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 agreement occurred on June 22, 2018. The Company believes that its existing cash and cash equivalents as of June 30, 2018 will be sufficient to fund its planned operations into the second 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 MD 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 primary brain tumors and brain metastases, pancreatic cancer and hematological malignancies. 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 in the United States and in Poland, and the timeframe in which such trials are completed; the ability of MD Anderson to successfully enroll patients in the Phase 1 clinical trial for 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---

<b>Moleculin Biotech, Inc.</b>		
<b>Unaudited Condensed Consolidated Balance Sheets (in thousands)</b>	<b>June 30, 2018</b>	<b>December 31, 2017</b>
Current Assets:		
Cash and cash equivalents	\$ 11,722	\$ 7,714
Prepaid expenses and other	1,170	588
Total current assets	12,892	8,302
Furniture and equipment, net	26	33
Intangible assets	11,148	11,148
Total Assets	<u>\$ 24,066</u>	<u>\$ 19,483</u>
Current Liabilities:		
Accounts payable and accrued expenses	\$ 3,515	\$ 1,712
Deferred compensation – related party	150	-
Warrant liability-current	451	503
Total current liabilities	4,116	2,215
Long-term deferred compensation - related party	-	150

Warrant liability - long term	3,202	-
Total Liabilities	7,318	2,365
Total Stockholders' Equity	16,748	17,118
Total Liabilities and Stockholders' Equity	<u>\$ 24,066</u>	<u>\$ 19,483</u>

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**Moleculin Biotech, Inc.**


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**Unaudited Condensed Consolidated Statements of Operations**


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	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
<b>(in thousands, except share and per share amounts)</b>				
Revenues	\$ -	\$ -	\$ -	\$ -
Operating Expenses:				
Research and development	4,231	515	5,469	1,199
General and Administrative and depreciation	1,227	805	2,626	1,657
Total operating expenses	<u>5,458</u>	<u>1,320</u>	<u>8,095</u>	<u>2,856</u>
Loss from operations	(5,458)	(1,320)	(8,095)	(2,856)
Other income (expense)				
Gain (loss) from change in fair value of warrant liability	331	(3,342)	1,040	(2,283)
Gain from settlement of liability	—	—	—	149
Gain from expiration of warrants	—	1,238	—	1,238
Other income (expense)	(1)	—	(1)	(1)
Interest income (expense), net	3	—	4	(1)
Net Loss	<u>\$ (5,125)</u>	<u>\$ (3,424)</u>	<u>\$ (7,052)</u>	<u>\$ (3,754)</u>
Net loss per common share - basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.19)</u>	<u>\$ (0.29)</u>	<u>\$ (0.23)</u>
Weighted average common shares outstanding - basic and diluted	<u>25,888,931</u>	<u>17,863,707</u>	<u>24,617,372</u>	<u>16,137,312</u>
Net Loss	(5,125)	(3,424)	(7,052)	(3,754)
Other comprehensive income (loss):				
Foreign currency translation	6	—	6	—
Comprehensive loss	<u>\$ (5,119)</u>	<u>\$ (3,424)</u>	<u>\$ (7,046)</u>	<u>\$ (3,754)</u>



Source: Moleculin Biotech, Inc.