

May 15, 2017



# Moleculin Biotech, Inc. Reports Financial Results for the First Quarter Ended March 31, 2017

HOUSTON, TX -- (Marketwired) -- 05/15/17 -- Moleculin Biotech, Inc. (NASDAQ: MBRX) ("Moleculin" or the "Company"), a preclinical pharmaceutical company focused on the development of anti-cancer drug candidates, some of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center ("MD Anderson"), today announced its financial and operating results for the first quarter ended March 31, 2017 and other recent developments.

## ***First Quarter & Recent Highlights***

### ***Annamycin***

- Appointed Theradex Systems, Inc. as its contract research organization ("CRO") for its planned Phase I/II clinical trial for Annamycin for the treatment of relapsed or refractory acute myeloid leukemia ("AML").
- Received Orphan Drug Designation by the U.S. Food and Drug Administration ("FDA") for the treatment of AML. The FDA grants orphan drug designation to drugs and biologics that are intended for the treatment of rare diseases that affect fewer than 200,000 people in the U.S. Orphan drug status is intended to facilitate drug development for rare diseases and may provide several benefits to drug developers, including tax credits for qualified clinical trial costs, exemptions from certain FDA application fees, and seven years of market exclusivity upon regulatory product approval.
- Recently filed the IND application for Annamycin, with a Phase I/II approach with the intent of increasing the Maximum Tolerable Dose ("MTD"). In subsequent discussions, the FDA requested certain revisions to the protocol, additional information, and additional data related to Chemistry, Manufacturing and Controls ("CMC"). The Company has the additional information, has made the requested revisions to the protocol, and is working on developing the CMC data. In the interim, Moleculin has withdrawn the IND application in order to resubmit it when the requested data are available. The Company believes that the resubmission of the IND application will occur in time for the IND to go into effect prior to the end of July 2017 and allow for clinical trials. However, if the Company is unable to obtain the required CMC data on a timely basis, it will be delayed in resubmitting its IND application, which will delay the commencement of the clinical trials for Annamycin beyond July 2017.
- Updated the Annamycin clinical strategy to add a Phase I arm to its next Phase II trial that leverages a potential increase in the MTD, which could increase the chance for positive outcomes. The Company believes that it will be able to publicly announce results from its Phase I/II clinical trial sometime in 2018.

## **WP1066**

- An MD Anderson physician is sponsoring a study of WP1066 for the treatment of brain tumors. While the Company is not participating in and has no influence on the conduct of this study, we understand that the sponsoring physician has submitted an IND to the FDA and the IND is on hold until documentation of Good Manufacturing Process or GMP production of WP1066 can be presented to the FDA, which Moleculin has agreed to provide. The Company expects that the sponsor's IND will move forward in 2017 and may produce publishable clinical results in 2018.
- Physician-scientists at another major US cancer center have requested and Moleculin has agreed to supply them with WP1066 for testing in a potential grant-funded clinical trial for children with Diffuse Intrinsic Pontine Gliomas (DIPG), a rare and very aggressive form of brain tumor. Studies conducted at this center have suggested that DIPG may be particularly sensitive to the inhibition of the activated form of a cell-signaling protein called STAT3, a primary target of WP1066, and their studies have demonstrated significant anti-tumor activity of WP1066 in DIPG in vitro and in vivo tumor models.

## **Corporate**

- Announced the closing of an underwritten public offering of securities for net proceeds of approximately \$4.5 million. Roth Capital Partners and National Securities Corporation acted as joint book-running managers. Subsequently, approximately \$0.8 million of additional funds have been received through the exercise of associated warrants issued in the offering bringing the total net raised in excess of \$5 million.
- Announced that Drs. Sandra Silberman and Paul Waymack have joined the Company's Scientific Advisory Board ("SAB"). The Company's current SAB also includes Dr. Waldemar Priebe (Chair) and Dr. Madeleine Duvic.

## **Planned Activities and Upcoming Potential Milestones**

Anticipated Milestone	Potential Timeframe
Announcement that our IND for Annamycin has become effective and that we may begin clinical trials	End of July 2017
IRB (Institutional Review Board) approvals and site initiations of various clinical sites participating in our Phase I/II clinical trial of Annamycin	Second Half of 2017
Establishment of a new MTD for Annamycin	Second Half of 2017
A clinician sponsored IND for WP1066 for treatment of adult brain tumors moving forward	Second Half of 2017
Announcement of Phase II data for Annamycin	2018
Announcement of further benefits of our sponsored research agreement with MD Anderson	2018

Walter Klemp, Chairman and CEO of Moleculin, stated: "We remain focused on developing the CMC data needed to submit our IND to move forward with the FDA by the end of July and to allow for clinical trials to begin. Additionally, we are pleased to have Theradex Systems as our CRO for our planned Phase I/II clinical trial for Annamycin. As we transition from a preclinical to a clinical stage company, we will continue to provide updates on our upcoming key milestones. We believe we have sufficient funds to pursue our planned operations into the first quarter of 2018."

## **Unaudited Financial Results for the Quarter Ended March 31, 2017**

Research and development (R&D) expense was \$0.68 million and \$0.02 million for the three

months ended March 31, 2017 and 2016, respectively. The increase of approximately \$0.66 million is mainly due to the Company becoming fully operational post its June 1, 2016 Initial Public Offering ("IPO"). The difference mainly consists of increases of \$0.15 million in sponsored research and research consultants, \$0.13 million in employee related costs, \$0.14 million in manufacturing and stability costs associated with the Company's IND application, \$0.1 million in regulatory counsel, \$0.07 million in costs associated with the Company's licenses, and \$0.07 million of other costs. This increased activity represents the Company's efforts in obtaining Orphan Drug designation for Annamycin and its associated IND application with the FDA.

General and administrative ("G&A") expense was \$0.85 million and \$0.31 million for the three months ended March 31, 2017 and 2016, respectively. The expense increase of approximately \$0.54 million is mainly due to the Company becoming fully operational post its June 1, 2016 IPO. Specifically, these increases were attributable to \$0.25 million associated with added headcount and associated payroll costs, \$0.23 million in legal, auditing, and accounting costs, and \$0.06 million in other G&A costs.

The Company recorded a gain of \$1.06 million in the first quarter of 2017 for the change in fair value on revaluation of its warrant liability associated with the warrants issued in conjunction with its stock offering on February 14, 2017. The Company is required to revalue certain of its 2017 warrants 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. A gain results principally from a decline in the Company's share price during the period and a loss results principally from an increase in the Company's share price.

During the period, the Company settled a previously incurred expense utilizing shares of its common stock with an attributed value of \$3.00 per share. The gain of \$0.15 million reflects the difference in the Company's share price in the open market as of the settlement date and \$3.00 per share.

Interest expense includes expense accrued on convertible promissory notes issued in 2015 and 2016 bearing interest at the rate of 8% per annum.

The net loss for the three months ended March 31, 2017 was \$0.33 million, which included the non-cash gains mentioned above aggregating to \$1.21 million. Excluding this amount, the net loss for the period was \$1.54 million, which is an increase of \$1.21 million over the previous years' \$0.33 million net loss. Included in both net loss numbers for the three months presented was \$0.11 million and \$0.00 million for the 2017 and 2016, respectively, in stock based compensation.

As of March 31, 2017, the Company had \$8.88 million of cash and cash equivalents compared to \$5.00 million at December 31, 2016. In February 2017, Moleculin completed a public offering of its common stock and warrants, pursuant to which it received approximately \$4.5 million in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. Additionally, during the three months ended March 31, 2017, \$0.80 million in cash was received due to warrants being exercised. Cash used in operations was \$1.39 million for the first quarter of 2017. The Company believes that its existing cash and cash equivalents as of March 31, 2017 continues to be sufficient to fund planned operations into the first quarter of 2018.

(Tables to follow)

***About Moleculin Biotech, Inc.***

Moleculin Biotech, Inc. is a preclinical stage pharmaceutical company focused on the development of anti-cancer drug candidates, some of which are based on discoveries made at M.D. Anderson Cancer Center. Our lead product candidate is Annamycin, an anthracycline for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML. We also have two preclinical small molecule portfolios, one of which is focused on the modulation of hard-to-target tumor cell signaling mechanisms and the recruitment of the patient's own immune system. The other portfolio targets 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. These statements relate to future events, future expectations, plans and prospects. Forward looking statements in this press release include our IND for Annamycin becoming effective so that we may begin clinical trials, our ability to receive the necessary IRB approvals to initiate our Phase I/II clinical trial of Annamycin, our ability to establish a new MTD for Annamycin, the ability of MD Anderson to move forward with an IND for WP1066 for treatment of adult brain tumors, our ability to announce grant funding for a clinical trial of WP1066 for treatment of rare childhood brain tumors, and our ability to announce Phase II data for Annamycin. 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.

**Moleculin Biotech, Inc.****Balance Sheets**

(in thousands except for par and share amounts)

	March 31, 2017 <u>(Unaudited)</u>	December 31, 2016 <u></u>
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 8,881	\$ 5,007
Prepaid expenses	269	215
Total current assets	<u>9,150</u>	<u>5,222</u>
<b>Long-Term Assets:</b>		
Furniture and equipment, net of accumulated depreciation of \$10 and \$6, respectively	19	23
Intangible assets	<u>11,148</u>	<u>11,148</u>
Total Assets	<u>\$ 20,317</u>	<u>\$ 16,393</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities:</b>		
Accounts payable and accrued expenses	\$ 858	\$ 1,069
Convertible notes payable	108	276
Warrant liability - current portion	<u>1,238</u>	<u>-</u>
Total current liabilities	2,204	1,345
Warrant liability	1,846	-
Long-term deferred compensation - related party	<u>125</u>	<u>88</u>
Total Liabilities	<u>4,175</u>	<u>1,433</u>
<b>Commitments and contingencies</b>		
<b>Stockholders' Equity:</b>		
Preferred stock, \$0.001 par value; 5,000,000 authorized, no shares issued and outstanding	-	-
Common stock, \$0.001 par value; 75,000,000 authorized, 17,756,862 and 12,164,852 shares issued and outstanding, respectively	18	12
Additional paid-in capital	21,128	19,623
Accumulated deficit	<u>(5,004)</u>	<u>(4,675)</u>
Total Stockholders' Equity	<u>16,142</u>	<u>14,960</u>
Total Liabilities and Stockholders' Equity	<u>\$ 20,317</u>	<u>\$ 16,393</u>

**Moleculin Biotech, Inc.**  
**Statements of Operations**  
**(Unaudited)**

(in thousands, except for share and per share amounts)

	Three Months Ended March 31,	
	2017	2016
Revenue	\$ —	—
Operating expenses:		
Research and development	683	15
General and administrative	848	306
Depreciation	4	—
Total Operating Expenses	1,535	321
Loss from operations	(1,535)	(321)
Other income (expense):		
Gain from change in fair value of warrant liability	1,059	—
Gain from settlement of liability	149	—
Other expense	(1)	—
Interest expense	(1)	(11)
Net loss	\$ (329)	\$ (332)
Net loss per common share - basic and diluted	\$ (0.02)	\$ (0.05)
Weighted average common shares outstanding - basic and diluted	14,590,220	6,717,767

Contact  
PCG Advisory Group  
Kirin Smith  
Chief Operating Officer  
D: 646.863.6519  
E: [ksmith@pcgadvisory.com](mailto:ksmith@pcgadvisory.com)

Source: Moleculin Biotech, Inc.