



Moleculin

Nasdaq: MBRX

Moleculin Biotech, Inc. Reports Financial Results for the Third Quarter Ended September 30, 2017

November 14, 2017 – Moleculin Biotech, Inc., (NASDAQ: MBRX) ("Moleculin" or the "Company"), a clinical stage 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, today announced its financial results for the third quarter ended September 30, 2017. Additionally, the Company announced potential upcoming milestones and recent corporate developments.

Walter Klemp, Chairman and CEO of Moleculin, commented, "We continue to make progress in advancing our drug candidates through their various regulatory approval pathways. We accomplished a number of important milestones on Annamycin, one of our lead cancer drug candidates. During the quarter, the Food and Drug Administration ("FDA") allowed our Investigational New Drug application ("IND") to proceed, meaning we could begin clinical trials of Annamycin for the treatment of relapsed or refractory Acute Myeloid Leukemia ("AML"). In preclinical tests, Annamycin has shown little to no cardiotoxicity and an ability to avoid the multidrug resistance mechanisms that often defeat the current first-line therapies for AML. For that reason, we believe Annamycin has the potential to become the first second-line therapy suitable for a majority of relapsed or refractory AML patients. Because first-line therapies fail in a significant majority of AML patients, we believe Annamycin may give new hope to those who have run out of treatment options.

We recently announced that 14 qualified cancer clinics have asked to participate in the Phase I/II clinical trial that is the subject of our IND, and that will study Annamycin for the treatment of relapsed or refractory AML. Seven of the interested sites are in Poland which we anticipate will give us access to a higher percentage of patients who are 'treatment naïve' patients. Study subjects who have not received any experimental therapies before entering our trial are important because we believe such patients may be in a better condition to respond positively to the Annamycin therapy. We have requested permission from the Polish government and we expect to receive authorization before the end of the year, at which point we plan to immediately begin enrolling patients.

We have several other drug candidates that are making progress in their respective development programs. We recently announced that the MD Anderson Cancer Center ("MD Anderson") has submitted an IND request to conduct a physician-sponsored Phase I clinical trial of WP1066 in patients with glioblastoma and melanoma that has metastasized to the brain. Preclinical testing suggests that WP1066 may increase the natural immune response to tumors, suppressing of tumor cell proliferation and tumor cell survival. If that IND is approved, we will then have two "clinical stage" programs under way.

During the quarter, we also announced that we have begun efforts to seek a Clinical Trial Authorization ("CTA") in Poland for the study of WP1220 (part of our WP1066 Portfolio) in the treatment of Cutaneous T-Cell Lymphoma. Additionally, we announced several collaborations, including an agreement with Mayo Clinic to study WP1066 for the treatment of a rare form of childhood brain tumor and two projects with the University of Bergen in Norway, one to conduct research on the ability of WP1122 to inhibit glycolysis and limit tumor growth and the other to dig more deeply into the potential ability of WP1066 to stimulate anti-cancer immune response. In addition, we announced research findings suggesting that one of our WP1122 analogs could be well suited for the treatment of pancreatic cancer."

"We believe one of the key strengths of Moleculin is the breadth and diversity of our drug development portfolio. We now have active development programs with four drug candidates representing three substantially different approaches to treating cancer."



"We believe one of the key strengths of Moleculin is the breadth and diversity of our drug development portfolio. We now have active development programs with four drug candidates representing three substantially different approaches to treating cancer."

--Walter Klemp
Chairman and CEO
of Moleculin Biotech



Jonathan Foster, Chief Financial Officer of Moleculin, stated, "I am pleased we have been able to raise \$8.7 million during the nine-month period ended September 30, 2017. As a result, we finished the third quarter with \$8.7 million in cash and cash equivalents and no debt, compared to \$5.0 million at December 31, 2016. During the third quarter we had a cash burn rate of approximately \$1.5 million, but anticipate the cash burn rate will increase as we move our cancer drugs into clinical trials. We are highly focused on running our business in an efficient manner, prudently managing our cash burn rate and maintaining a solid cash position."

Third Quarter Highlights and Recent Corporate Developments

Moleculin Appoints Dr. Sandra Silberman as Chief Medical Officer - New Products - November 8, 2017, the Company announced the appointment of Dr. Sandra Silberman as Chief Medical Officer ("CMO") in charge of New Products.

Moleculin Announces MD Anderson has Filed an IND with the FDA on its Drug WP1066 for the Treatment of Brain Tumors - November 1, 2017, the Company announced that responses have been submitted to FDA requests for additional information relating to the physician-sponsored IND application to study WP1066 as a potential treatment for brain tumors.

Moleculin Requests Authorization from the Polish Government to Advance Annamycin - October 24, 2017, the Company announced that it has submitted its request for CTA in Poland which, if allowed, will enable a clinical trial to study Annamycin for the treatment of relapsed or refractory AML in Poland. This will be in addition to the previously announced allowance of Moleculin's IND filing with the FDA.

Moleculin Announces 14 Qualified Clinical Sites Requesting Participation in Annamycin Trial - October 18, 2017, the Company announced that 14 qualified cancer clinics have requested to participate in its clinical trial to study Annamycin for the treatment of relapsed or refractory AML.

Moleculin Announces Strategic Collaboration to Develop Immune Stimulation Drug - October 11, 2017, the Company announced that it has entered into an agreement to collaborate with the University of Bergen to expand research on WP1066 and early indications of a possible dual ability to increase immune system response to tumors while also suppressing tumor cell proliferation tumor cell and survival.

Moleculin Signs Agreement with First Hospital for Annamycin Trials - October 3, 2017, the Company announced it has entered into an agreement with the first of several hospitals desiring to become treatment sites for its clinical trial to study Annamycin for the treatment of relapsed or refractory AML.

Moleculin Announces FDA Approval of Annamycin IND - September 26, 2017, the Company announced that the FDA has allowed Moleculin's IND for the study of Annamycin in relapsed or refractory AML to proceed. This allows Moleculin to begin clinical trials of Annamycin in the US.

Moleculin Engages CRO to Begin Clinical Trials of WP1220 for the Treatment of Cutaneous T-Cell Lymphoma - September 13, 2017, the Company announced it has engaged contract research organization ("CRO") Bioscience SA ("Bioscience") to prepare for a proof-of-concept clinical trial in Poland to study Moleculin's drug candidate WP1220 for the treatment of cutaneous T-cell lymphoma.

Moleculin to Collaborate on Combining its WP1122 Brain Cancer Drug Candidate with Roche's Drug Avastin - September 6, 2017, the Company announced it has entered into a collaborative agreement with the University of Bergen in Norway to study WP1122 in combination with the drug Avastin® (bevacizumab) made by Roche Pharma. Roche Pharma is not a party to the collaborative agreement.

Moleculin Begins Clinical Testing Site Development Efforts in Poland; Selects Bioscience SA as Polish CRO - August 3, 2017, the Company announced it has selected Bioscience SA, a Polish CRO to begin identifying and preparing clinical testing sites in Poland for Annamycin, the Company's drug candidate for the treatment of relapsed or refractory AML.

Moleculin Strengthens Board of Directors with Appointment of John M. Climaco - July 27, 2017, the Company announced the appointment of John M. Climaco as an independent member of the Company's Board of Directors, effective July 24, 2017 to fill a board vacancy.

Moleculin Signs Agreement with MD Anderson Cancer Center for Leukemia Drug, Annamycin - July 18, 2017, the Company announced it has signed a new technology license agreement with MD Anderson based on new patent applications Moleculin intends to file relating to its drug Annamycin for the treatment of relapsed or refractory AML.

Moleculin Appoints Lead European Principal Investigator for Planned Annamycin Clinical Trial - July 6, 2017, the Company announced it has appointed Dr. Lidia Gil of Poznan University of Medical Sciences in Poznan, Poland to be the lead European Principal Investigator for its upcoming planned Phase I/II clinical trial of Annamycin for the treatment of relapsed or refractory AML, subject to receipt of Polish approval of the CTA.

Upcoming Potential Milestones

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	Second Half of 2017
Establishment of a new RP2D for Annamycin	First Half of 2018
A clinician sponsored IND for WP1066 for treatment of adult brain tumors moving forward	Second Half of 2017
Announcement of Clinical Data for Annamycin trial	2018
Announcement of further benefits of our sponsored research agreement with MD Anderson	2018

Third Quarter Results

Research and Development Expense. Research and development (R&D) expense was \$1.1 million and \$0.5 million for the three months ended September 30, 2017 and 2016, respectively. The increase of approximately \$0.6 million mainly represents an increase of approximately: \$0.1 million related to an increase in R&D associated headcount costs, \$0.1 million for sponsored research and related expenses; and, approximately \$0.4 million associated with developing and testing drug product as we prepare our IND for Annamycin and for the related clinical trials.

General and Administrative Expense. General and administrative expense was \$1.3 million and \$0.9 million for the three months ended September 30, 2017 and 2016, respectively. The expense increase of approximately \$0.4 million was mainly attributable to

the increase in headcount and associated payroll costs of \$0.2 million, \$0.3 million of stock based compensation; and, approximately \$0.1 million in legal, accounting, consulting, and other professional expenses. This was offset by a reduction in public listing expenses of \$0.2 million.

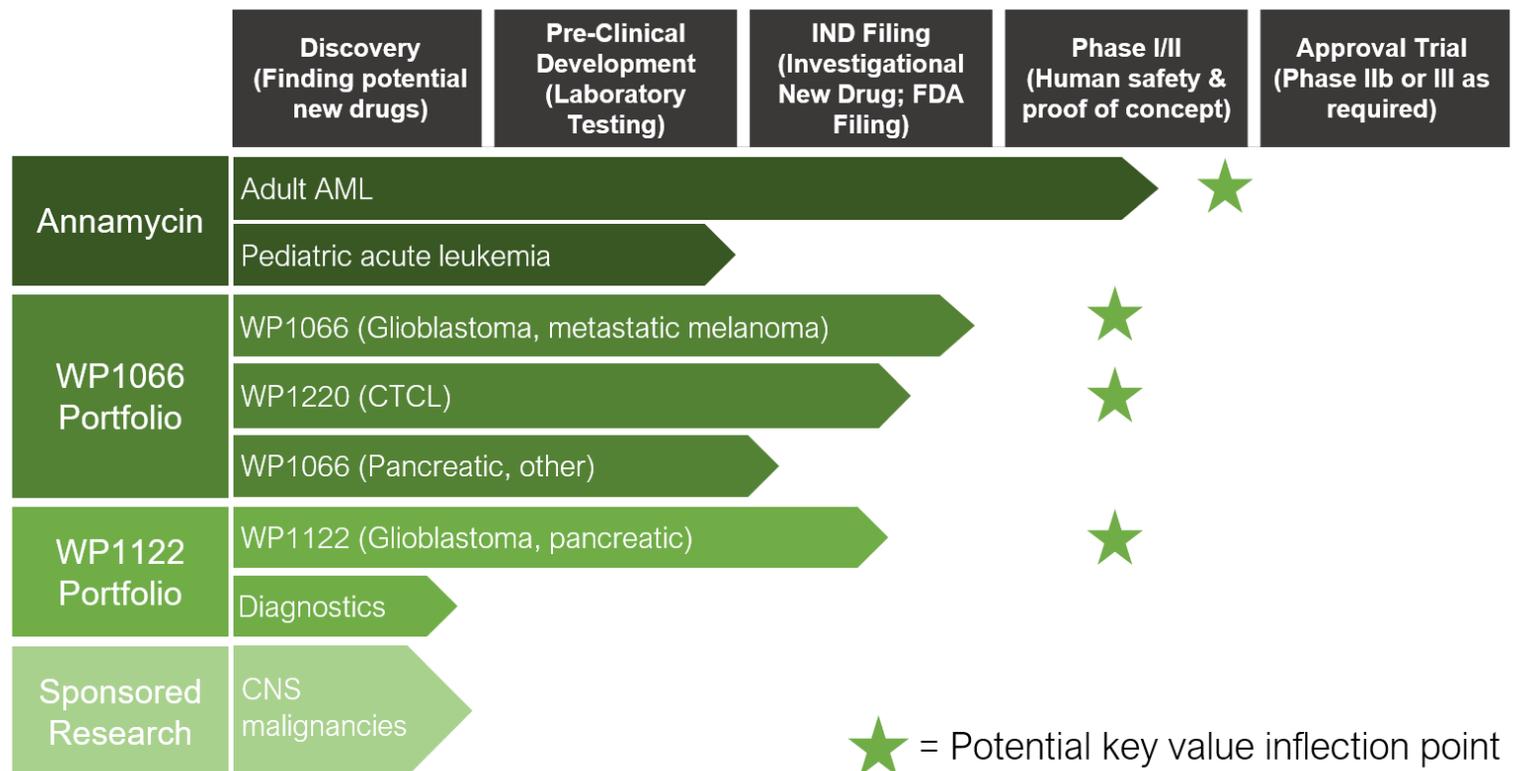
Net Loss. The net loss for the three months ended September 30, 2017 was \$2.9 million which included non-cash income of \$0.5 million related to a gain recognized on the expiration of warrants. The net loss also included additional noncash charges for \$0.5 million for stock based compensation and other stock based expenses.

Liquidity and Capital Resources

As of September 30, 2017, we had \$8.7 million in cash and cash equivalents compared to \$5.0 million at December 31, 2016. In February 2017, we completed a public offering of our common stock and warrants, pursuant to which we received approximately \$4.5 million in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. Additionally, through September 30, 2017, \$3.3 million in cash was received from the exercise of warrants issued in our February public offering and \$0.4 million from the sale of common stock in our ATM offering. Cash used in operations was \$4.9 million for the nine months ended September 30, 2017. This increase over the prior year of \$2.3 million was mainly due to an increase in

headcount and general company activity as it prepared its IND for Annamycin and readied for the related, upcoming trials. We believe that our existing cash and cash equivalents as of September 30, 2017 and cash generated already in the third quarter will be sufficient to fund our planned operations into the third quarter of 2018. Such plans are subject to change depending on clinical enrollment progress and use of drug product.

Development Pipeline



About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical 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 being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML. We also have two preclinical small molecule portfolios in development, 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>.

Moleculin Biotech, Inc.
Balance Sheets
 (in thousands except for par and share amounts)

	<u>September 30, 2017</u>	<u>December 31, 2016</u>
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,736	\$ 5,007
Prepaid expenses and other	727	215
Total current assets	9,463	5,222
Furniture and equipment, net of accumulated depreciation of \$14 and \$6, respectively	22	23
Intangible assets	11,148	11,148
Total assets	\$ 20,633	\$ 16,393
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,089	\$ 1,069
Convertible notes payable	—	276
Warranty liability	743	—
Total current liabilities	1,832	1,345
Long-term deferred compensation – related party	150	88
Total liabilities	1,982	1,433
Commitments and contingencies (Note 7)	—	—
Stockholders' equity		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 75,000,000 shares authorized, 20,822,214 issued outstanding at September 30, 2017 and 12,164,852 issued and outstanding at December 31, 2016	21	12
Additional paid-in capital	29,925	19,623
Accumulated deficit	(11,295)	(4,675)
Total stockholders' equity	18,651	14,960
Total liabilities and stockholders' equity	\$ 20,633	\$ 16,393

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	1,061	497	2,260	616
General and administrative	1,338	924	2,987	1,848
Depreciation	5	1	13	2
Total operating expenses	<u>2,404</u>	<u>1,422</u>	<u>5,260</u>	<u>2,466</u>
Loss from operations	<u>(2,404)</u>	<u>(1,422)</u>	<u>(5,260)</u>	<u>(2,466)</u>
Other income (expense):				
Loss from change in fair value of warrant liability	(470)	—	(2,753)	—
Gain from settlement of liability	—	—	149	—
Gain from expiration of warrants	—	—	1,238	—
Other income	9	—	8	—
Interest expense	<u>(1)</u>	<u>(10)</u>	<u>(2)</u>	<u>(37)</u>
Net loss	<u>\$ (2,866)</u>	<u>\$ (1,432)</u>	<u>\$ (6,620)</u>	<u>\$ (2,503)</u>
Net loss per common share – basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.12)</u>	<u>\$ (0.37)</u>	<u>\$ (0.28)</u>
Weighted average common shares outstanding – basic and diluted	<u>20,534,720</u>	<u>11,579,239</u>	<u>17,683,441</u>	<u>9,066,804</u>

Moleculin Biotech, Inc.
Statements of Cash Flows
(Unaudited)
 (in thousands)

	Nine Months Ended September 30,	
	2017	2016
Cash Flows from Operating Activities:		
Net loss	\$ (6,620)	\$ (2,503)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	13	2
Stock-based compensation	487	209
Deferred CEO compensation	62	88
Change in fair value of warrant liability	2,753	—
Gain in settlement of liability	(149)	—
Gain from expiration of warrants	(1,238)	—
Other	(9)	—
Changes in operating assets and liabilities:		
Prepaid expenses	(518)	(245)
Accounts payable and accrued expenses	285	(147)
Net Cash Used in Operating Activities	(4,934)	(2,596)
Cash Flows from Investing Activities:		
Purchase of fixed assets	(12)	(10)
Purchase paid for acquisition of Moleculin, LLC, net with cash acquired	—	(100)
Net Cash Used in Investing Activities	(12)	(110)
Cash Flows from Financing Activities:		
Proceeds from notes payable	—	165
Payments on note payable	—	(470)
Proceeds from exercise of warrants	3,808	—
Proceeds from sale of common stock units, net of cash stock issuance costs	4,867	9,167
Net Cash Provided by Financing Activities	8,675	8,862
Net change in cash and cash equivalents	3,729	6,156
Cash and cash equivalents, at beginning of period	5,007	28
Cash and cash equivalents, at end of period	\$ 8,736	\$ 6,184
Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ 2	\$ 48
Cash paid for income taxes	\$ —	\$ —
Supplemental disclosure of non-cash investing and financing activities:		
Common stock issued for conversion of debt	\$ 302	\$ 342
Common stock issued for services provided	\$ 89	\$ —
Common stock issued to acquire Moleculin, LLC	\$ —	\$ 9,774

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 willingness of the FDA to allow the physician-sponsored IND request as amended and the willingness and ability of MD Anderson to begin a Phase 1 clinical trial with WP1066 and the ability of WP1066 to show safety and efficacy in patients with glioblastoma or melanoma that has metastasized to the brain . 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.

Contacts

Joe Dorame, Robert Blum or Joe Diaz
Lytham Partners, LLC
602-889-9700
mbrx@lythampartners.com