

May 23, 2017



Moleculin Biotech Issues Shareholder Update on FDA Designation of Orphan Drug and IND Status for Annamycin

HOUSTON, TX -- (Marketwired) -- 05/23/17 -- 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 that it has issued the following letter to its shareholders.

Letter to Shareholders

Update on FDA Designation of Orphan Drug and IND Status for Annamycin

May 23, 2017

Dear Moleculin Shareholders,

We wish to thank you for your interest and investment in Moleculin Biotech, Inc. This letter is intended to update you on recent and planned activities at Moleculin. As an overview, we recently received Orphan Drug designation from the Food and Drug Administration (FDA) for Annamycin and we continue to make progress toward submitting an IND for Annamycin for the treatment of relapsed or refractory adult AML. As well, the deadline for exercise of short-term warrants connected with our recent offering of common stock has now passed, removing over 5 million shares of overhang from our stock.

Potential

As we transition from a preclinical to a clinical-stage company, it is important to keep in mind the potential we see for Annamycin. The good news for AML patients currently is that bone marrow transplants are successful in curing AML about 80% of the time. The bad news, however, is that patients must first completely clear their bone marrow blasts (tumor cells) before qualifying for a transplant and the "induction therapy" used to do so only succeeds about 20% of the time. That leaves about 80% of AML patients without hope because there is no approved second-line therapy once the first-line therapy fails.

The magnitude of the unmet need in the treatment of AML is evidenced by the recent purchase of Celator (CPXX) by Jazz Pharmaceuticals (JAZZ). Celator's lead product was a reformulation of the current first-line induction therapy for AML, referred to as "7+3" into a single injectable liposome. This improved delivery method of the same old 7+3 drugs (known as cytarabine and daunorubicin) resulted in an increase in the average overall survival of AML patients by 3.5 months. Shortly after the announcement of this potential improvement, Jazz paid \$1.5 billion for Celator. Importantly, we believe Annamycin has the

potential to represent an even greater improvement for AML patients.

As summarized from our more recent annual report for the year ended December 31, 2016 on Form 10-K (Annual Report) filed with the Security and Exchange Commission (SEC), in a previous Phase I clinical trial of Annamycin, conducted by a prior developer of Annamycin, in relapsed or refractory adult AML patients, 8 of 16 patients demonstrated significant activity, with 6 of 14 patients completely clearing their bone marrow blasts (the primary benchmark for qualifying for a curative bone marrow transplant). The reason only 14 (rather than 16) patients were tested for leukemic bone marrow blasts is that 2 of 16 patients succumbed to their disease before bone marrow testing should be completed. Furthermore, in a 30-patient dose-ranging Phase I/II study in Acute Lymphoblastic Leukemia, 3 of 8 patients treated with the MTD cleared their leukemic blasts to a level sufficient to qualify for a bone marrow transplant. We should note that these patients had failed multiple prior induction therapy attempts with first-line therapy prior to receiving Annamycin. Although we can provide no assurance regarding the performance of Annamycin in future clinical trials, if these results can be reproduced in the general population of AML patients, we may be able to more than double the number of patients who qualify for a curative bone marrow transplant.

We believe Annamycin's activity in relapsed or refractory patients may be possible because it appears capable of avoiding the multidrug resistance mechanisms that work against the currently approved drugs like daunorubicin. And, at the same time, currently approved drugs like daunorubicin are significantly cardiotoxic (dosing must be limited due to the potential for immediate and permanent damage to the heart). In contrast, Annamycin has shown little to no cardiotoxicity in over 100 patients treated. We believe these characteristics make Annamycin a promising candidate to become the first ever second-line therapy for relapsed or refractory AML, presenting a unique opportunity to request a pathway for accelerated approval.

Our other technologies also continue to demonstrate potential as well. In particular, WP1066 is the subject of a physician-sponsored IND application submitted to the FDA by MD Anderson Cancer Center. Although that application was placed on hold pending the development of additional CMC data, we are optimistic that this IND might be allowed in the second half of this year, giving us two clinical stage drugs. In addition, a second major cancer treatment center has asked to be able to use WP1066 in a potential grant-funded clinical trial for a rare form of childhood brain tumors.

Notwithstanding our belief in the potential for Annamycin, many risks and uncertainties exist regarding the successful development of Annamycin and our other technologies, which have been set forth in our most recent Annual Report and, more recently, in our Form 10-Q for the first quarter of 2017, both filed with the Security and Exchange Commission (both available on the Company's website www.moleculin.com or at www.sec.gov). We encourage you to read and understand these risks carefully.

Progress

The Orphan Drug designation granted to Annamycin as of March of this year for the treatment of AML (Acute Myeloid Leukemia) represents a significant development milestone for Moleculin. The FDA grants Orphan Drug designation to investigational drugs to facilitate drug development for rare diseases, which may provide several benefits to Moleculin, including assistance with clinical study design and drug development, tax credits for qualified clinical trial costs, exemptions from certain FDA application fees, and seven years of market

exclusivity in the US upon regulatory product approval.

We filed our IND (Investigational New Drug) application on February 10, 2017. In subsequent discussions, the FDA requested certain revisions to the protocol, additional information, and additional data related to Chemistry, Manufacturing and Controls (CMC). We have the additional information, we have made the requested revisions to the protocol, and we are developing the CMC data. In the interim, we withdrew the IND application so that we may resubmit it when the requested data becomes available. We are working to resubmit the IND application in time for the IND to go into effect and to announce that we may begin Phase I/II clinical trials by the end of July of 2017. However, if we are unable to obtain the required CMC data on a timely basis, we will be delayed in resubmitting our IND application, which will delay the commencement of our clinical trials.

On February 14th of this year, we raised \$4.5 million (net of offering costs) through the sale of 3,710,000 units, priced at a public offering price of \$1.35 per unit, with each unit consisting of one share of common stock, a five-year Series A warrant to purchase 0.50 of a share of common stock, a 90-day Series B warrant to purchase one share of common stock, and a five-year Series C warrant to purchase 0.50 of a share of common stock, which Series C warrant only vested if, and to the extent that, the Series B warrant was exercised during the 90-day exercise period. To date, approximately 600,000 Series B Warrants have been exercised, providing approximately \$800,000 of additional proceeds to the Company. As of May 15th, the remaining Series B warrants have now expired, as well as the unvested Series C Warrants connected with them. As a result, market overhang of over 5 million shares was eliminated, leaving long-term warrants for approximately 2.6 million shares related to this transaction outstanding, which includes warrants issued in connection with a partial exercise of the over-allotment option we granted to the underwriter in the offering, as well as warrants issued as compensation to the underwriter in the offering. For a detailed discussion about this offering, please refer to our recently filed Form 10-Q for the quarter ended March 31, 2017.

We believe this additional fund-raising provides us with enough cash to support our development efforts into the first quarter of 2018, at which point we hope to have made significant progress with clinical trials for Annamycin. In the meantime, several key development milestones are expected, beginning with the announcement of our IND for Annamycin before the end of July 2017. From there, we expect to announce the opening of specific clinical sites as we gain IRB (Institutional Review Board) approvals for our protocol and, once sufficient patients have been recruited, the establishment of an MTD (Maximum Tolerable Dose) signaling the advancement beyond Phase I activity. We currently expect the MTD to be established during the second half of 2017.

Additional potential milestones for the second half of 2017 include the possibility of a physician-sponsored IND being allowed for WP1066 for the treatment of brain tumors, as well as additional development progress resulting from our continuing sponsored research at MD Anderson Cancer Center in 2018.

Milestones

We are about to enter an exciting phase for our company and we encourage you to watch for the following potential announcements marking key milestones for Moleculin:

Anticipated Milestone	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

Thank you again for your support and we look forward to reporting further progress soon regarding Annamycin and the rest of Moleculin's development pipeline. If you have any questions in the meantime, please email us at info@moleculin.com. For additional information regarding Moleculin, please visit our web site at <http://www.moleculin.com/>.

Best regards,

/s/

Walter Klemp,
Chairman and CEO

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 letter 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 letter 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 letter speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this letter to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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