

March 24, 2021



# Moleculin Biotech, Inc. Reports Financial Results for the Year Ended December 31, 2020

HOUSTON, March 24, 2021 /PRNewswire/ -- Moleculin Biotech, Inc., (Nasdaq: MBRX) (Moleculin or the Company), a clinical stage pharmaceutical company with a broad portfolio of drug candidates targeting highly resistant tumors and viruses, today announced its financial results for the year ended December 31, 2020 and provided a business update.



## Recent Milestones and Accomplishments:

### Corporate Strategy and Events

Raised gross proceeds of approximately \$81 million through registered equity offering and ATM program in 1Q21 providing runway into 2025 based on the Company's current R&D spending levels. The Company may expand its R&D expenditures to take advantage of new opportunities within its broad pipeline and/or increase the speed of its clinical trials. At a minimum however, the Company intends for current cash levels to support an operating runway through at least 2023.

### Next Generation Anthracycline - Annamycin

- Received \$1.5 million grant to fund a Phase 1b/2 clinical trial for the treatment of soft tissue sarcoma ("STS") lung metastases in Europe
- Received FDA IND and ODD for Annamycin against STS; plan to begin a Phase 1b/2 clinical trial in the US for patients after receiving first-line therapy for STS that has metastasized to the lungs
- Reached a 2nd dose limiting toxicity (DLT) in March 2021 and plan to establish a maximum tolerable dose (MTD) in our European trial for Annamycin against acute myeloid leukemia (AML); plan to pursue Phase 2 once the recommended Phase 2 dose (RP2D) is established
- Presented animal data at American Society for Hematology showing Annamycin's synergistic activity against AML when used in combination with the Ara-C; based on

this data we plan a potential Phase 1/2 trial with Annamycin in combination with Ara-C on AML in 2021

### **Immune/Transcription Modulators - WP1066 Portfolio**

- Reported positive interim results in Emory University pediatric brain tumor Phase 1 clinical trial; DIPG patient showed an apparent response in first cohort
- Advanced WP1066 for GBM in adults to fourth and final cohort in dose escalation trial at MD Anderson; notified physician sponsoring trial is leaving MD Anderson; pursuing IND transfer and continuation of research
- Received "Rare Pediatric Disease" designation from FDA for WP1066; entitles Moleculin to receive a transferrable Priority Review Voucher upon New Drug Approval for any one of three different brain tumor indications

### **Infectious Disease and Metabolism/Glycosylation Inhibitors- WP1122, WP1096 and WP1097 Portfolio**

- Multiple positive pre-clinical in-vitro studies on WP122 in its potential ability to address COVID-19
- Positive in vitro results demonstrating the antiviral activity of WP1096 and WP1097 in a range of infectious diseases including: SARS-CoV-2, HIV, Zika and Dengue Fever
- Working to initiate a Phase 1a/1b clinical trial in COVID-19 or a physician-sponsored clinical trial for a cancer indication, or both in 2021

### **Anticipated 2021 Milestones**

- Potential for 8 clinical trials in 2021, including 3 to be conducted by Moleculin and 5 primarily externally funded and conducted trials; External funding will be relied upon to the extent it is available

### **Management Discussion**

"We are extremely pleased by the progress we made over the past year despite headwinds from the global COVID-19 pandemic. 2020 proved to be a pivotal year for the Company as we progressed our clinical trials and expanded our product pipeline. Although we are still in the early months of 2021, we are excited to see this momentum build, as we have raised approximately \$81 million in the first quarter, which will enable us to further pursue our pipeline with expanded pre-clinical and clinical activities, through at least 2023," commented Walter Klemp, Chairman and CEO of Moleculin.

"We continue to see tremendous progress and promise across our three primary drug candidates, which have accounted for five Phase 1 clinical trials either completed or under way to date. Our lead candidate Annamycin, our "Next Generation Anthracycline" designed to avoid multidrug resistance mechanisms, received an independent assessment last year, which confirmed the absence of cardiotoxicity in patients treated in both our US and European open label and single arm Phase 1/2 clinical trials for acute myeloid leukemia. We

were pleased to conclude our US Phase 1/2 clinical trial of Annamycin in AML, and following discussions with the FDA, will focus on establishing a recommended Phase 2 Dose and generating requested safety and efficacy data within our European trial in Poland. In our European trial, we are currently treating patients in the 5th cohort at 240 mg/m<sup>2</sup>. Dose limiting toxicities relating to liver function have now been noted at this level sufficient to establish an upper limit of dosing. We are planning to amend the protocol for this trial to allow exploration of an intermediate dose level between the 210 mg/m<sup>2</sup> dose in the fourth cohort and the current 240 mg/m<sup>2</sup> dose level, in order to establish the maximum tolerated dosage (MTD) and Recommended Phase 2 dose (RP2D), which may be the same. As soon as the RP2D is established, we intend to begin a Phase 2 expansion phase to assess the efficacy of Annamycin as a single agent. In addition, as a result of our preclinical research showing potential synergistic effect from combining Annamycin with Ara-C (a drug commonly used as a single agent and in combination chemotherapy for AML), we also intend to begin the Phase 1 portion of an AML trial using Annamycin in combination with Ara-C.

While we are pleased by our continued development of Annamycin in AML, we are also excited by the encouraging results observed in Annamycin's ability to treat lung metastases. Sponsored research has demonstrated that Annamycin is capable of accumulating in the lungs in animal models at concentration levels up to 34-fold higher than doxorubicin, the current standard of care chemotherapy for a range of lung metastases. This research has also shown that Annamycin has activity in several different lung metastases, including sarcoma, colorectal cancer and triple negative breast cancer. Most recently, we announced that Annamycin demonstrated a potentially significant therapeutic benefit against metastatic osteosarcoma in a preclinical animal study. In this preclinical study, computerized tomography scans showed that animals treated with Annamycin exhibited significant suppression of tumor growth. Further, not a single death was observed in the treated animals, whereas significant tumor burden contributed to the rapid death of 90% of untreated animals. As of day 130 in the trial, the survival rate for animals treated with Annamycin was 100%, compared with only 10% for untreated animals. We have received both Investigational New Drug ("IND") status, and Orphan Drug Designation ("ODD") for Annamycin, allowing us to begin a Phase 1b/2 clinical trial in the US for patients with soft tissue sarcoma (STS) that has metastasized to the lungs after first-line therapy for their disease. To manage the upcoming Phase 1/2 Study in the US, we selected Catalyst Clinical Research as our contract research organization. Our efforts in progressing Annamycin in lung metastasis have also paved the way for a second European trial in 2021, as our license partner recently received a \$1.5 million grant from Agencja Badań Medycznych in Poland to fund a Phase 1b/2 clinical trial of Annamycin for the treatment of soft tissue sarcoma lung metastases in Europe.

We also continued to drive the clinical development of WP1066, the lead molecule in Moleculin's portfolio of immune stimulators and modulators of transcription. WP1066 is currently in two US physician-sponsored Phase 1/2 clinical trials, one at MD Anderson for the treatment of glioblastoma ("GBM") in adults and the second at Emory University for the treatment of pediatric brain tumors. In our Phase 1 clinical trial of WP1066 for the treatment of brain tumors in children being conducted at the Aflac Cancer & Blood Disorders Center at Children's Healthcare of Atlanta, the first cohort of patients was treated with no adverse events related to treatment and the trial has progressed full enrollment of the second cohort at a dose level of 6mg/kg. Notably, within the first cohort, one patient with diffuse intrinsic

pontine glioma ("DIPG") showed an apparent response to the treatment with both clinical improvement and radiologic reduction of tumor size; we are particularly encouraged by this apparent response as approximately 200 clinical trials have been conducted in DIPG, and no drug to date has been able to show significant activity in this disease.

In our trial at MD Anderson, WP1066 is in the fourth and final cohort in the dose escalation phase. We were notified during the first quarter of 2021 that the physician sponsoring this trial is leaving MD Anderson. Although we cannot be assured that this trial will continue at MD Anderson after her departure, we have requested that MD Anderson have the IND for this trial transferred into our name to help ensure the potential continuation of this important research. While we are making arrangements to pursue this research in additional physician-sponsored trials, we expect that continued research on WP1066 in adult GBM will be temporarily delayed in 2021.

In addition to WP1066, we see meaningful opportunity in WP1220, which is an analog of WP1066, in treating cutaneous T-cell lymphoma ("CTCL"). The US market for CTCL had estimated sales of \$40 million in 2020 and consisted of technologies that are as much as 40 years old. The data from our WP1220 Proof of Concept Trial for the treatment of CTCL, while limited in patient size, was promising; WP1220 demonstrated an objective response rate of 45%, with no adverse events and 55% stable disease, resulting in 100% clinical benefit. Given the tremendous market opportunity and these strong early indications of efficacy, we plan to seek a collaborative partner to support a Phase 2 clinical study of WP1220 in CTCL in 2021.

While we continue to drive the further development of our drugs that are showing meaningful activity in cancer indications, we believe our WP1122 portfolio holds tremendous opportunity for creating long-term shareholder value in the area of infectious disease. In 2020, WP1122 demonstrated its unique mechanism of action and in-vitro activity in numerous preclinical studies and independent research. We believe the preclinical work conducted and under way for WP1122 will support an IND application or its equivalent in other countries for either cancer-related or virus-related clinical trials (or both) during the first half of 2021. Although our initial preclinical focus for the WP1122 program was to help provide a treatment for the growing COVID-19 pandemic, we discovered that two other molecules within our portfolio of antimetabolites displayed significant in vitro antiviral activity against SARS-CoV-2 and other hard to treat viruses. Independent laboratory testing of our drug candidates, WP1096 and WP1097, not only showed significant antiviral activity against SARS-CoV-2, but also showed greater potential against HIV, Zika, and Dengue Fever. We caution that the above data is preclinical and there is no assurance that we will see similar results in our planned clinical trials."

Mr. Klemp concluded, "Our strategy since founding Moleculin has been to deliver long term shareholder value through our 'multiple shots on goal strategy'. Following our recent capital raise in the first quarter of 2021, we are now optimally positioned to deliver on this strategy, with cash runway through at least 2023, and the potential to see 8 clinical trials this year on our drug candidates."

### **Financial Results for the Year Ended December 31, 2020**

Research and development ("R&D") expense was \$12.8 million and \$11.0 million for the years ended December 31, 2020 and 2019, respectively. The increase in R&D of \$1.8

million was primarily driven by increased clinical trial activity (3 drugs in 4 clinical trials in 2019, versus 3 drugs in 5 clinical trials in 2020), increased costs related to sponsored research agreements, costs related to manufacturing of additional drug product, and two additional employees in R&D headcount.

General and administrative ("G&A") expense was \$6.8 million and \$6.3 million for the years ended December 31, 2020 and 2019, respectively. The increase in G&A of \$0.5 million was mainly attributable to increased payroll related costs for an additional finance staff, increased stock-based compensation expense, and increased costs for officer's liability insurance being partially offset by reduced travel expenses due to the COVID-19 pandemic.

Net loss for the year ended December 31, 2020 was \$17.4 million, which included non-cash gains of \$2.3 million on warrants in 2020 as compared to \$4.1 million in the prior year and approximately \$1.7 million of stock-based compensation expense in 2020 as compared to \$1.5 million in 2019.

### **Liquidity and Capital Resources**

We believe that our cash resources as of December 31, 2020, along with the additional funding received subsequent to year-end, will be sufficient to meet our projected operating requirements, based on our current use of cash, through at least the year 2023. Such projections are subject to changes in our internally funded preclinical and clinical activities, including unplanned preclinical and clinical activity.

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

Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the development of a broad portfolio of oncology drug candidates for the treatment of highly resistant tumors and viruses. The Company's clinical stage drugs are: Annamycin, a Next Generation 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, WP1066, an Immune/Transcription Modulator capable of inhibiting p-STAT3 and other oncogenic transcription factors while also stimulating a natural immune response, targeting brain tumors, pancreatic cancer and hematologic malignancies, and WP1220, an analog to WP1066, for the topical treatment of cutaneous T-cell lymphoma. Moleculin is also engaged in preclinical development of additional drug candidates, including other Immune/Transcription Modulators, as well as WP1122 and related compounds capable of Metabolism/Glycosylation Inhibition.

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, our expected cash runway; establishing a recommended Phase 2 Dose for Annamycin in 2021; the timing of the commencement and progress of the clinical trials conducted by Moleculin and by third parties; the ability of Moleculin to find a collaborative

partner to support a Phase 2 clinical study of WP1220 in CTCL in 2021; and the ability to file for W1122 an IND application or its equivalent for either cancer-related or virus-related clinical trials in the first half of 2021. 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 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

James Salierno / Carol Ruth  
The Ruth Group  
973-255-8361 / 917-859-0214  
[jsalierno@theruthgroup.com](mailto:jsalierno@theruthgroup.com)  
[cruth@theruthgroup.com](mailto:cruth@theruthgroup.com)

## -- Financial Tables Follow--

<b>Moleculin Biotech, Inc.</b>		
<b>Unaudited Condensed Consolidated Balance Sheets</b>		
<b>(in thousands)</b>	<b>December 31, 2020</b>	<b>December 31, 2019</b>
Current assets:		
Cash and cash equivalents	\$ 15,173	\$ 10,735
Prepaid expenses and other current assets	2,025	2,749
Total current assets	17,198	13,484
Furniture and equipment, net	483	316
Intangible assets	11,148	11,148
Operating lease right-of-use asset	202	287
Total assets	<u>\$ 29,031</u>	<u>\$ 25,235</u>
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	\$ 2,920	\$ 3,570
Total current liabilities	2,920	3,570
Operating lease liability - long-term, net of current portion	159	276
Warrant liability - long term	8,192	5,818
Total liabilities	11,271	9,664
Total stockholders' equity	17,760	15,571
Total liabilities and stockholders' equity	<u>\$ 29,031</u>	<u>\$ 25,235</u>

**Unaudited Condensed Consolidated Statements of Operations**

(in thousands, except share and per share amounts)	Year Ended December 31,	
	2020	2019
Revenues	\$ —	\$ —
Operating expenses:		
Research and development	12,757	11,013
General and administrative and depreciation	6,985	6,511
Total operating expenses	19,742	17,524
Loss from operations	(19,742)	(17,524)
Other income:		
Gain from change in fair value of warrant liability	2,346	4,062
Other income, net	28	15
Interest income, net	13	13
Net loss before taxes	\$ (17,355)	\$ (13,434)
Income tax benefit	—	229
Net loss	\$ (17,355)	\$ (13,205)
Net loss per common share - basic and diluted	\$ (1.76)	\$ (1.95)
Weighted average common shares outstanding - basic and diluted	9,845,685	6,786,901

View original content to download multimedia <http://www.prnewswire.com/news-releases/moleculin-biotech-inc-reports-financial-results-for-the-year-ended-december-31-2020-301254611.html>

SOURCE Moleculin Biotech, Inc.