

March 19, 2020



Moleculin Biotech, Inc. Reports Financial Results for the Year Ended December 31, 2019

HOUSTON, March 19, 2020 /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, announced its financial results for the year ended December 31, 2019 and provided a business update.



Management Discussion

Walter Klemp, Chairman and CEO of Moleculin, stated, "2019 marked a pivotal year for Moleculin, as we achieved several key milestones in our three core technologies and six oncology drug candidates, strengthened our financial position, and bolstered our leadership team. Notably, we are extremely excited by the progress we made advancing our lead candidate, Annamycin, a 'next generation anthracycline' demonstrating little to no cardiotoxicity. In the recently completed Phase 1 portion of our US Phase 1/2 clinical trial in AML, Annamycin met its primary endpoint and demonstrated a clean safety profile with no evidence of cardio-toxicity when delivered to patients at or below the lifetime maximum anthracycline dose established by the FDA. These findings were consistent with an independent review of Annamycin, in which the independent expert concluded that he 'does not see evidence of cardio-toxicity.' We are looking forward to further advancing this trial in 2020, as the FDA has already granted Annamycin Fast Track status and Orphan Drug Designation for AML. We plan to discuss with the FDA a plan to accelerate our approval pathway for a pivotal Phase 2 trial by relying on our European trial to establish a recommended Phase 2 dose, which we believe will be the fastest and most efficient way for us to enter Phase 2. We also look forward to filing an Investigational New Drug (IND) application for the treatment of tumor metastases to the lung in 2020."

Mr. Klemp continued, "We are also pleased by the progress made in both our WP1066 and WP1122 programs. In our WP1066 portfolio, Emory University received FDA approval for their IND status request for our STAT3 Inhibitor in a pediatric brain tumor clinical trial. This approval enables us to explore a new approach for treating pediatric brain cancer. Pre-clinical research at Emory demonstrated WP1066's significant anti-tumor effect on medulloblastoma cell lines, and we are very encouraged to continue to explore this potential solution for treating this rare condition. Additionally, we reported positive data from the

Phase 1 'proof-of-concept' clinical trial with WP1220 for the treatment of cutaneous T-cell lymphoma (CTCL), which demonstrated a median reduction of 56% in skin cancer lesions. We also made great strides within our WP1122 portfolio where we began preclinical testing of a new approach to Pancreatic cancer, by attacking cancer through inhibiting tumor metabolism. "

Mr. Klemp concluded, "We are excited to build off the tremendous progress made in 2019 across our entire drug portfolio. We believe we are well positioned to continue the momentum in 2020 and look forward to the upcoming WP1066 trial at Emory University, advancing WP1220 into a Phase 2 clinical trial, and the potential accelerated FDA approval pathway and Phase 2 trial of Annamycin. And, this momentum has taken on a new dimension with our recent announcement of our agreement with UTMB to test WP1122 for antiviral properties on many viruses, including Coronavirus. We continue to work diligently towards our near-term goals of delivering on Phase 2 clinicals trial for WP1220 and our 'next generation anthracycline,' Annamycin. We look forward to sharing our progress throughout the year."

Recent Milestones and Accomplishments:

Next Generation Anthracycline - Annamycin

- Received positive independent report confirming absence of cardiotoxicity (unlike currently approved anthracyclines)
- Announced positive results and successful completion of the Phase 1 portion of the AML Phase 1/2 trial in the US and plans to seek accelerated FDA approval for pivotal Phase 2 trial in AML
- Found to be active against tumor metastases to the lung in pre-clinical testing
- Confirmed anti-tumor efficacy of Annamycin in AML through new animal data
- Expanded production to support positive clinical activity
- Received FDA Fast Track designation and filed for new patents covering the production and reconstitution of Annamycin

Immune/Transcription Modulators - WP1066 Portfolio

- Emory University received FDA Approval of IND for STAT3 inhibitor in Investigator Initiated Clinical Trial
- Filed for patent protection on behalf of MD Anderson covering combination of immune-stimulating/transcriptional modulator, including combination with radiation therapy
- Received Emory University Clinical Trial Review Committee approval in pediatric brain tumor trial
- Presented preclinical pancreatic cancer data at American Association for Cancer Research Annual Meeting
- Received Orphan Drug Designation from FDA

Metabolism/Glycosylation Inhibitors - WP1122 Portfolio

- Final data from Phase 1 proof-of-concept clinical trial for the treatment of cutaneous T-cell lymphoma
- Began preclinical testing of new approach to Pancreatic cancer, opportunity to attack cancer by inhibiting tumor metabolism

- Entered into an agreement with University of Texas Medical Branch at Galveston (UTMB) to conduct research on WP1122, and other molecules of the Company, for antiviral properties against a range of viruses, including Coronavirus

Corporate Strategy

- Entered into sublicense agreement with WPD Pharmaceuticals requiring WPD to provide a minimum of \$4 million in development expenditures over a four-year period
- Appointed Dr. Martin Tallman, Chief of Leukemia of Memorial Sloan Kettering Cancer Center, and Dr. James L. Abbruzzese, Chief of Medical Oncology Division at Duke University, to Science Advisory Board
- Appointed Dr. Hongbo Zhai, former Senior Faculty and Supervisor of Postdoctoral Fellow at University of California San Francisco, to Science Advisory Board

Anticipated 2020 Milestones

- First patient treated in the Phase 1 clinical trial with WP1066 for the treatment of pediatric brain tumors at Emory University
- IND submission for Annamycin for the treatment of tumor metastases to the lung
- Pre-IND Meeting with FDA/EMA concerning a Phase 2 clinical trial with WP1220 for the treatment of CTCL
- File IND/CTA for a Phase 2 clinical trial with WP1220 for the treatment of CTCL
- FDA End of Phase 1 meeting for Annamycin in AML
- Achieving an MTD or a dose level at or above 300 mg/m² in EU AML Phase 1/2 trial for Annamycin
- Benefit from non-dilutive financial funding for additional clinical trials

Financial Results for the Year Ended December 31, 2019

Research and development ("R&D") expense was \$11.0 million and \$9.7 million for the years ended December 31, 2019 and 2018, respectively. The increase in R&D of approximately \$1.3 million mainly relates to: increased clinical trial activity (2 drugs in 3 clinical trials in 2018, versus 3 drugs in 4 clinical trials in 2019) including the manufacturing of additional drug product and the issuance of common stock for \$0.5 million, related to the exercise of the option to reacquire certain license rights in Germany under the Dermin License Agreements. These increases were offset by a reduction of \$0.7 million in various other R&D expenses.

General and administrative ("G&A") expense was \$6.3 million and \$5.2 million for the years ended December 31, 2019 and 2018, respectively. The increase in G&A of approximately \$1.1 million was mainly attributable to an increase in payroll costs for additional finance and office staff, stock-based compensation expense for vested warrants issued to a consultant, and annual employee stock options.

The net loss for the year ended December 31, 2019 was \$13.2 million, which included non-cash expenses of approximately \$1.5 million of stock-based compensation in 2019 as compared to \$1.1 million in 2018.

Liquidity and Capital Resources

As of December 31, 2019, we had cash and cash equivalents of \$10.7 million and prepaid expenses and other of \$2.7 million. We also had \$2.2 million of accounts payable and \$1.4 million of accrued expenses. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our clinical trials. For the years ended December 31, 2019 and 2018, we used approximately \$17.2 million and \$12.2 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. The increase in 2019 reflects the increase in clinical and preclinical activity over 2018. For the year ended December 31, 2019, net proceeds from financing activities were \$20.9 million, predominately from the sale of our common stock and warrants. In 2018, approximately \$12.0 million was raised predominately through the sale of shares of common stock and the exercise of warrants. Cash used in investing activities for the year ended December 31, 2019 was approximately \$0.05 million primarily for the purchases of employee computer equipment and office furniture.

We believe that our cash resources as of December 31, 2019, along with the additional funding received subsequent to year-end, will be sufficient to meet our projected operating requirements towards the end of the third quarter of 2020. This expectation does not consider unplanned preclinical and clinical activity, additional funding, including but not limited to, equity issuances including the use of the Lincoln Park or ATM facilities.

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. 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, the ability of Moleculin to successfully recruit sufficient patients to complete its current clinical trials; the ability of Moleculin to be permitted by the FDA to accelerate its approval pathway for a pivotal Phase 2 trial by relying on its European trial to establish a recommended Phase 2 dose; and the ability of Moleculin to file an IND for the treatment of cancer metastases to the lung in 2020. 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

646-536-7028 / 7000

jsalierno@theruthgroup.com

cruth@theruthgroup.com

-- Financial tables follow --

Moleculin Biotech, Inc.			
Unaudited Condensed Consolidated Balance Sheets		December 31	
(in thousands)	2019	2018	
Current Assets:			
Cash and cash equivalents	\$ 10,735	\$ 7,134	
Prepaid expenses and other current assets	2,749	840	
Total current assets	13,484	7,974	
Furniture and equipment, net	316	463	
Intangible assets	11,148	11,148	
Operating lease right-of-use asset	287	—	
Total Assets	\$ 25,235	\$ 19,585	
Current Liabilities:			
Accounts payable and accrued expenses and other current liabilities	\$ 3,570	\$ 3,698	
Warrant liability - current	—	180	
Total current liabilities	3,570	3,878	
Operating lease liability - long-term, net of current portion	276	—	
Deferred rent - long-term	—	107	
Warrant liability - long term	5,818	1,328	
Total Liabilities	9,664	5,313	
Total Stockholders' Equity	15,571	14,272	
Total Liabilities and Stockholders' Equity	\$ 25,235	\$ 19,585	

Unaudited Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)	Year Ended December 31,	
	2019	2018
Revenues	\$ —	\$ —
Operating Expenses:		
Research and development	11,013	9,728
General and Administrative and depreciation	6,511	5,297
Total operating expenses	17,524	15,025
Loss from operations	(17,524)	(15,025)
Other income (expense):		
Gain from change in fair value of warrant liability	4,062	3,185
Other income (expense)	15	(40)
Interest income, net	13	4
Net Loss before taxes	\$ (13,434)	\$ (11,876)
Income tax benefit	\$ 229	\$ —
Net loss	\$ (13,205)	\$ (11,876)
Net loss per common share - basic and diluted	\$ (0.32)	\$ (0.46)
Weighted average common shares outstanding - basic and diluted	40,721,406	25,904,170

View original content to download multimedia <http://www.prnewswire.com/news-releases/moleculin-biotech-inc-reports-financial-results-for-the-year-ended-december-31-2019-301027153.html>

SOURCE Moleculin Biotech, Inc.