

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 8-K
CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

DATE OF REPORT (DATE OF EARLIEST EVENT REPORTED): May 14, 2019



MOLECULIN BIOTECH, INC.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE
(State or Other Jurisdiction of Incorporation or Organization)

001-37758
(Commission File No.)

47-4671997
(I.R.S. Employer Identification No.)

5300 Memorial Drive, Suite 950, Houston, TX 77007
(Address of principal executive offices and zip code)

(713) 300-5160
(Registrant's telephone number, including area code)
(Former name or former address, if changed from last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol (s)	Name of each exchange on which registered
Common Stock, par value \$.001 per shares	MBRX	The NASDAQ Stock Market LLC

Item 2.02 Results of Operations and Financial Condition.

On May 14, 2019, Moleculin Biotech, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2019 and recent operational highlights. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

[99.1](#) [Press release dated May 14, 2019](#)

SIGNATURE

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MOLECULIN BIOTECH, INC.

Date: May 14, 2019

By: /s/ Jonathan P. Foster
Jonathan P. Foster
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press release dated May 14, 2019
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Moleculin Biotech, Inc. Reports Financial Results for the First Quarter Ended March 31, 2019

HOUSTON - May 14, 2019 - 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, today announced its financial results for the first quarter ended March 31, 2019. Additionally, the Company announced potential upcoming milestones and recent corporate developments.

Management Discussion

Walter Klemp, Chairman and CEO of Moleculin, said, "We are off to a very good start in 2019, as we have achieved significant milestones with the development of our oncology portfolio. This time last year we had just commenced our first clinical trial for one drug. Today, we have three drugs in four clinical trials under way with a fifth clinical trial that may start before year end. We are excited with the progress that has been achieved and we expect that 2019 will be the 'year of data' where we provide progress reports as our various drug candidates proceed through their respective clinical trials."

"One of the highlights of the just completed quarter was FDA 'Fast Track' designation for Annamycin, our drug candidate for the treatment of adults with relapsed or refractory acute myeloid leukemia. Fast Track represents an important first step toward accelerated approval. We presented the FDA a proposal for the designation, and they determined that Annamycin should be eligible for accelerated approval. This potentially cuts years off our development timeline and should make Annamycin attractive to development partners much sooner. We also announced pre-clinical data supporting the expansion of Annamycin indications to include lung cancer."

"It bears noting we announced last week that our Annamycin clinical trial in Poland is generating very encouraging results," continued Mr. Klemp. "We have completed the first cohort of the trial and 2 out of 3 patients treated responded sufficiently to qualify for a potentially curative bone marrow transplant. Although we are still early in the trial, we believe this small sample size is indicative of what Annamycin is designed to produce. The standard of care failed these relapsed or refractory patients, and we believe Annamycin has provided new hope for an improved quality of life, and, or possibly, an extension of life."

"We continue to see strong anti-tumor activity with WP1066, our flagship Immune/Transduction Modulator in a wide range of animal models. The data is showing positive results of combining our drug candidate WP1066 with checkpoint inhibitors, suggesting that WP1066 may have the ability to improve the outcome of immune checkpoint therapy in tumors that have been resistant to these therapies. We believe this represents an important new approach to treating many types of cancer. We are extremely excited with the ongoing results of this preclinical research. These important developments, along with regulatory approvals, complement our vision of developing numerous drugs that support our 'multiple shots on goal' strategy."

"Also, during the quarter, the FDA granted Orphan Drug Designation for WP1066 for the treatment of glioblastoma, one of the most aggressive forms of brain tumors. The FDA grants Orphan Drug Designation to drugs and biologics that are intended for the treatment of rare diseases. In addition to glioblastoma, WP1066 could be effective in the treatment of a range of highly resistant tumors including acute myeloid leukemia ("AML") and pancreatic cancer."

Mr. Klemp concluded, "This just completed first quarter yielded a number of important developments that set the stage for a successful 2019 and the years ahead. As we continue through our various clinical trials and preclinical research, we are heartened with the tangible progress being made and that we are advancing toward our goal of developing effective treatments for rare and difficult cancers that eclipse the outcomes of the standard of care. Providing hope to patients, where it might have been lost, is a driving force for the entire Moleculin team."

Recent milestones and accomplishments include:

Next Generation Anthracycline - Annamycin

- Announcement of additional positive interim safety and efficacy data from our ongoing study of Annamycin in Poland. After receiving a single starting dose of 120 mg/m² in the first cohort of the dose escalation phase of the trial, 2 of 3 patients treated responded sufficiently to qualify for a potentially curative bone marrow transplant. Additionally, no patients in the U.S. or in the European trials, to date, have shown any signs of cardiotoxicity. The results for all 3 patients were reviewed by the Safety Review Committee, which determined that no drug-related adverse events were observed that would prevent advancing the trial to the next higher dose level of 150 mg/m².
- FDA grants Fast Track Designation of our drug Annamycin for the treatment of relapsed or refractory acute myeloid.
- Announcement that we have found Annamycin to be active against metastases to the lungs in pre-clinical testing. Annamycin significantly improved survival in an aggressive form for triple negative breast cancer metastasized to the lungs in animal models.
- U.S. clinical trial completed the first cohort and is currently recruiting patients for the second cohort to be given a dose level of 120 mg/m².

Immune/Transcription Modulators - WP1066 Portfolio

- Agreement with Emory University to conduct pediatric brain tumor trial. This will be a Phase 1 clinical trial of WP1066 in children with recurrent or refractory malignant brain tumors. The study will be conducted at the Aflac Cancer & Blood Disorders Center at Children's Healthcare of Atlanta.
- Announcement that preclinical data supporting activity of our STAT3-inhibiting Immune/Transcription Modulators was presented by Dr. Waldemar Priebe, Founder and Chair of the Scientific Advisory Board of Moleculin, Inc. at the 2019 Annual Meeting of the American Association for Cancer Research ("AACR") in Atlanta, GA. The presentation included data resulting from preclinical evaluation in pancreatic cancer models of STAT3 inhibitors WP1066 and WP1732. WP1066 is an orally bioavailable drug with significant brain uptake that is currently in Phase I clinical studies in patients with brain tumors. Complementary to WP1066, we believe STAT3 inhibitor WP1732 may be suitable for IV administration and demonstrates high uptake by the pancreas without uptake to the brain.
- Announcement of the first two patients enrolled in our European clinical trial of WP1220 for the topical treatment of cutaneous T-Cell Lymphoma (CTCL).
- FDA granted Orphan Drug Designation for our drug candidate WP1066 for the treatment of glioblastoma, the most aggressive form of brain tumor.

- Announcement that we have shown that WP1066, an Immune/Transduction Modulator, appears to counteract resistance to checkpoint blockade therapy (specifically, immune checkpoint target PD-L1) in our own sponsored research.

General

- Announcement of Dr. Martin Tallman, Chief of Leukemia for Memorial Sloan Kettering Cancer Center has joined the Company's Science Advisory Board (SAB).

Jonathan Foster, Executive Vice president and Chief Financial Officer of Moleculin, stated, "We finished the first quarter with cash of approximately \$8.8 million and we received additional gross proceeds of \$16.6 million subsequent to the quarter end from a public offering and the exercise of various warrants. The strengthening of our balance sheet provides us the ability to fund our ongoing research programs and clinical trials. We believe our existing cash and cash equivalents will be sufficient to fund our planned operations well into 2020. Currently, we have four clinical trials ongoing, and we will continue to carefully focus on being capital efficient through this important developmental process."

Anticipated Milestones

Anticipated Milestones	Potential Timeframe
Next Generation Anthracycline - Annamycin	
Initial IRB (Institutional Review Board) approvals and site initiations of various clinical sites participating in our Phase 1/2 clinical trial of Annamycin	Accomplished and ongoing 2019
Complete cohort of 150 mg/m ² - prior trial recommended Phase II dose (RP2D)	2019 (Starting in Europe)
Start treating patients in Annamycin Phase 1/2 clinical trial in Poland	Accomplished and ongoing 2019
Announcement of initial clinical data for Annamycin trial	Accomplished and ongoing 2019
Announced completed first cohort of 120 mg/m ² in Poland and 100 mg/m ² in the U.S.	Accomplished
Poland clinical trial (MB-105) begins Phase 2	2020
Approach FDA on U.S. trial (MB-104) regarding dose expansion using Poland trial data	2020
Announced FDA grants Fast Track Designation to Annamycin for treatment of relapsed or refractory acute myeloid leukemia (AML)	Accomplished
Immune/Transcription Modulators - WP1066 Portfolio	
Announced FDA grants Orphan Drug Designation to WP1066 for treatment of glioblastoma	Accomplished
Announcement of initial clinical data from WP1066 clinician sponsored trial	2019
Phase 1 surgical cohort begins in MD Anderson clinical trial of WP1066 for brain tumors	Second Half of 2019
Transfer clinician MD Anderson-sponsored WP1066 IND to Molculin	Second Half of 2019
Emory Physician Led Pediatric Medulloblastoma Trial begins	Second Half of 2019
Announcement of further benefits of our sponsored research agreement with MD Anderson	Accomplished and Ongoing into 2019
Announced filing and approval of Clinical Trial Authorization for WP1220 for the treatment of cutaneous T-cell lymphoma (CTCL) in Poland	Accomplished
Assess WP1220 initial patient data	Q4-2019
IND for WP1732 submitted	2020
Dose first patient in Phase I trial for WP1732	2020
Announce further preclinical research results on WP1066 portfolio	Accomplished and ongoing 2019
Metabolism/Glycosylation Inhibitors - WP1122 Portfolio	
Begin preclinical work on WP1122	Accomplished
File IND for WP1122	2020
General Clinical	
Announce a fourth approved clinical trial	Accomplished
Announce a fifth approved clinical trial	2019

First Quarter Highlights and Recent Corporate Developments

Moleculin Announces Additional Positive Interim Results in First Cohort of Phase 1/2 Clinical Studies of Annamycin in Acute Myeloid Leukemia in Europe - 2 of 3 patients qualify to proceed to a potentially curative bone marrow transplant; trial advances to next higher dose level May 7, 2019, the Company announced additional positive interim safety and efficacy data from its ongoing open label, single arm Phase 1/2 study of Annamycin in Poland. After receiving a single starting dose of 120 mg/m² in the first cohort of the dose escalation phase of the trial, 2 of 3 patients treated responded sufficiently to qualify for a potentially curative bone marrow transplant. The results for all 3 patients were reviewed by the Safety Review Committee, which determined that no drug-related adverse events were observed that would prevent advancing the trial to the next higher dose level of 150 mg/m². To date in the European trial, one patient experienced grade 2 mucositis (which resolved to grade 1 within 2 days) and no other adverse events related to Annamycin have been reported. No additional patient data have been developed in the Company's parallel US clinical trial, which is currently recruiting its second cohort to be given a dose level of 120 mg/m² (the U.S. trial started at a lower initial dose of 100 mg/m²).

Moleculin Announces \$15.0 Million Registered Direct Offering April 23, 2019, the Company announced that it has entered into definitive agreements with institutional investors to purchase an aggregate of 9,375,000 units at a public offering price of \$1.60 per unit in a registered direct offering, which offering was closed on April 25, 2019. Each unit is comprised of one share of common stock and 0.5 of a warrant to purchase one share of common stock. Each warrant has an exercise price of \$1.75 per share and is exercisable immediately. The warrants will expire five years from the date of issuance. The gross proceeds of the offering were approximately \$15.0 million, prior to deducting the placement agent fees and other estimated offering expenses.

Moleculin Receives FDA Approval of Fast Track Designation for Annamycin April 18, 2019, the Company announced that the FDA has approved its request for Fast Track Designation for its drug, Annamycin, for the treatment of relapsed or refractory AML.

A drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers;
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met;
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

Moleculin Announces Significant Discovery in Lung Cancer Models *Annamycin Found to be Active Against Metastases to the Lungs in Pre-Clinical Testing* - April 17, 2019, the Company announced that its ongoing sponsored research at The University of Texas MD Anderson Cancer Center has now demonstrated that Annamycin is able to significantly improve survival in an aggressive form of triple negative breast cancer metastasized to the lungs in animal models. The Company believes its success in increasing the survival rate in mice with this tumor model in combination with the previously observed high uptake of Annamycin by the lungs is a promising indication that supports additional clinical research in lung and metastatic lung cancers.

Moleculin Announces Agreement with Emory University to Conduct Pediatric Brain Tumor Trial April 11, 2019, the Company announced it has entered into an agreement with Emory University to conduct a Phase 1 clinical trial of WP1066 in children with recurrent or refractory malignant brain tumors. The study will be conducted at the Aflac Cancer & Blood Disorders Center at Children's Healthcare of Atlanta.

Moleculin Announces Preclinical Pancreatic Cancer Data Presented at American Association for Cancer Research Annual Meeting April 3, 2019, the Company announced that preclinical data supporting activity of its STAT3-inhibiting Immune/Transcription Modulators was presented by Dr. Waldemar Priebe, Founder and Chair of the Scientific Advisory Board of Moleculin, Inc. at the 2019 Annual Meeting of the American Association for Cancer Research in Atlanta, GA.

AACR Abstract:

<https://www.moleculin.com/inhibition-of-stat3-in-pancreatic-ductal-adenocarcinoma-and-immunotherapeutic-implications/>

The presentation included data resulting from preclinical evaluation in pancreatic cancer models of STAT3 inhibitors WP1066 and WP1732, both discovered at The University of Texas MD Anderson Cancer Center and licensed by Moleculin. WP1066 is an orally bioavailable drug with significant brain uptake that is currently in Phase 1 clinical studies in patients with brain tumors. Complementary to WP1066, we believe STAT3 inhibitor WP1732 may be suitable for IV administration and demonstrates high uptake by the pancreas without uptake to the brain.

Moleculin Announces Pricing of Underwritten Public Offering March 27, 2019, the Company announced the pricing of an underwritten public offering of an aggregate of 5,250,000 units at a public offering price of \$1.00 per unit, which offering was closed on March 29, 2019. Each unit is comprised of one share of common stock and 0.5 of a warrant to purchase one share of common stock for a total of 5,250,000 shares of common stock and warrants to purchase 2,625,000 shares of common stock. Each warrant has an exercise price of \$1.10 per share and is exercisable immediately. The warrants will expire five years from the date of issuance. The gross proceeds of the offering were \$5.25 million, prior to deducting the underwriting discount and other estimated offering expenses.

Moleculin Announces First Patients Enrolled in Lymphoma Clinical Trial March 19, 2019, the Company announced that the first two patients have been enrolled in its European clinical trial of WP1220 for the topical treatment of cutaneous T-cell lymphoma (CTCL). The Company is targeting CTCL with a topical p-STAT3 inhibitor in light of the significant role that STAT3 appears to play in CTCL skin lesions. The intent is to take an early read on the first five patients in this trial to assess whether the activity supports an expansion of clinical testing of this topical drug. The Company expects preliminary data to be available during 2019.

Moleculin Announces Memorial Sloan Kettering Chief of Leukemia Joins Science Advisory Board March 18, 2019, the Company announced that Dr. Martin Tallman, Chief of Leukemia for Memorial Sloan Kettering Cancer Center has joined the Company's Science Advisory Board (SAB).

Moleculin Announces Outlicensing Deal to Accelerate Preclinical and Clinical Development February 20, 2019, the Company announced that it has entered into a sublicense agreement with WPD Pharmaceuticals (WPD), located in Poland. The agreement provides WPD with exclusive rights, subject to current license agreements, to develop and market a range of Moleculin's technologies in certain European countries (which does not include the UK, France, Italy and Spain) in exchange for contributing a minimum of \$4 million in development expenditures agreed upon by Moleculin during the term of the agreement plus an

ongoing royalty on future revenues. The agreement is specifically geared to provide Moleculin with the benefit of European Union (EU) grant funding, which may be available to companies like WPD that are formed and present in EU countries.

Moleculin Announces Approval for Third Drug to Commence Clinical Trials*MBRX will now have three distinctive oncology drugs in clinic in four ongoing clinical trials - WP1220, a STAT3 inhibitor, to begin clinical trials in Poland for the treatment of CTCL, a rare and deadly skin cancer* - February 07, 2019, the Company announced it has received approval to begin clinical trials in Poland for its Immune/Transduction Modulator, WP1220, for the topical treatment of CTCL. CTCL is a potentially deadly form of skin cancer involving skin lesions that often have high levels of activated STAT3 (p-STAT3). As a potent inhibitor of p-STAT3, the Company believes WP1220 may be ideally suited to treat these lesions through topical application, which is what this clinical trial is designed to evaluate. The Company has three unique drug candidates in four ongoing clinical trials for the potential treatment of rare and difficult cancers.

Moleculin Announces the FDA has Granted Orphan Drug Designation for its Brain Tumor Drug February 05, 2019, the Company announced that the FDA has granted Orphan Drug Status for its drug candidate WP1066 for the treatment of glioblastoma, the most aggressive form of brain tumor. The Company believes that WP1066 represents a new class of drugs which it calls "Immune/Transduction Modulators" because it has demonstrated the ability in preclinical testing in animals to both stimulate a natural immune response to tumors and directly attack tumor cells by inhibiting multiple key oncogenic transcription factors, including STAT3, HIF1- α and c-Myc.

In addition to the glioblastoma trial at MD Anderson, the Company has received interest from additional investigators, including Emory University and Mayo Clinic for conducting clinical trials for the treatment of pediatric brain tumors, as well as others interested in treating a range of highly resistant tumors including AML and pancreatic cancer.

Moleculin Announces Dr. James L. Abbruzzese, Chief of Medical Oncology Division at Duke University, Joins Science Advisory Board*Dr. Abbruzzese to add significant pancreatic cancer expertise to advance drug development* - January 17, 2019, the Company announced that Dr. James L. Abbruzzese, Chief of Oncology at Duke University has joined Moleculin's Science Advisory Board. Dr. Abbruzzese is recognized as one of the world's leading experts in the clinical study and treatment of pancreatic cancer and the addition of his expertise will be invaluable to the Company's efforts in developing a potential treatment for pancreatic cancer.

Moleculin Announces Positive Data for its Pancreatic Cancer Drug Candidate*WP1732 - now second lead drug demonstrating enhanced activity in combination with immune checkpoint blockade antibodies* - January 03, 2019, the Company announced that in preliminary animal studies, a second of its lead drugs, water-soluble, WP1732, has demonstrated enhanced activity in combination with checkpoint blockade antibodies in pancreatic cancer. This is significant for several reasons. It shows that this is a consistent capability across the Company's platform of Immune/Transduction Modulators and it further supports independent research suggesting that STAT3 may be a key to enabling checkpoint blockade activity in otherwise resistant tumors. Importantly, though, when coupled with its recent findings that WP1732 accumulates disproportionately in the pancreas, the Company believes it points to WP1732 as a potentially pivotal new approach to treating pancreatic cancer. Expansion of the WP1732 and WP1066 in vivo studies are in progress.

Financial Results for the First Quarter ended March 31, 2019

Research and Development Expense. Research and development ("R&D") expense was \$2.9 million and \$1.2 million for the three months ended March 31, 2019 and 2018, respectively. The increase of approximately \$1.7 million is mainly related to the increase in clinical activity and slight increase in R&D headcount over the prior period.

General and Administrative Expense. General and administrative expense was \$1.6 million and \$1.4 million for the three months ended March 31, 2019 and 2018, respectively. The increase of approximately \$0.2 million was mainly attributable to an increase in G&A related payroll costs, as well as increases in stock-based compensation costs attributable to new employees and new employee stock options.

Net Loss. The net loss for the three months ended March 31, 2019 was \$4.0 million, which included non-cash income of \$0.5 million on the gain in fair value of our warrant liability, which was offset by non-cash charges of \$0.3 million related to stock-based compensation and other stock-based expenses.

Liquidity and Capital Resources

As of March 31, 2019, the Company had cash and cash equivalents of \$8.8 million. Subsequent to the three months ended March 31, 2019, the Company received gross proceeds of approximately \$16.6 million, as a result of a completed public offering and the exercise of various warrants from past public offerings.

Cash used in operations was \$3.8 million for the three months ended March 31, 2019. This \$1.0 million increase over the prior year of \$2.8 million was mainly due to: 1) developing, manufacturing and testing drug product as we prepared for clinical trials; 2) an increase in R&D headcount and associated payroll costs; 3) an increase in sponsored research and related expenses; and 4) an increase in license fees. These are all a reflection of the increased clinical and pre-clinical activity and the associated increase in G&A support for our three core drug technologies as compared to the prior year.

In March 2019, the Company completed an underwritten offering of 5,250,000 units, each unit consisting of one share of common stock, and 0.5 of a warrant to purchase one share of common stock. The public offering price of the units was \$1.00 per unit, and the underwriter agreed to purchase the units from the Company at a price of \$0.93 per Unit. The warrants included in the units are immediately exercisable at a price of \$1.10 per share, subject to adjustments in certain circumstances, and will expire five years from the date of issuance. The net proceeds from the transaction was approximately \$4.65 million after deducting the underwriting discount and estimated offering expenses.

Subsequent to the three months ended March 31, 2019, on April 23, 2019, the Company entered into definitive agreements with institutional investors to purchase an aggregate of 9,375,000 units at a public offering price of \$1.60 per unit in a registered direct offering. Each unit is comprised of one share of common stock and 0.5 of a warrant to purchase one share of common stock resulting in gross proceeds of \$15.0 million. Each warrant has an exercise price of \$1.75 per share and is exercisable immediately. The warrants will expire five years from the date of issuance. The offering closed on April 25, 2019.

Also, 1,408,018 shares were issued due to the exercise of various warrants related to past public offerings, subsequent to March 31, 2019 and through the date of filing of these financial statements. Gross proceeds received due to these exercises approximated \$1.6 million.

The Company believes that its existing cash and cash equivalents as of March 31, 2019, combined with the additional funds raised via the issuance of equity described above, will be sufficient to fund planned

operations into the second quarter of 2020. Any additional issuances should extend the funding of our planned operations significantly beyond the second quarter of 2020. Such plans are subject to our stock price, market conditions, changes in planned expenses depending on clinical enrollment progress, the use of drug product or a combination thereof.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical-stage pharmaceutical company focused on the treatment of highly resistant cancers. Moleculin has three core technologies, all of which are based on discoveries made at M.D. Anderson Cancer Center by Dr. Waldemar Priebe and his team. The Company's clinical-stage drugs are Annamycin, a Next Generation Anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML, and WP1066, an Immune/Transcription Modulator targeting brain tumors, pancreatic cancer and AML. The Company is also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as Metabolism/Glycosylation Inhibitors. Moleculin's Next Generation Anthracycline, Annamycin, we believe, is unlike any currently approved anthracyclines, as it is designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity. Annamycin has preliminary clinical data suggesting its potential to become the first successful therapy suitable for the majority of relapsed or refractory AML patients and is currently in two Phase I/II clinical trials. WP1066 is one of several Immune/Transcription Modulators capable of stimulating immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs) while also inhibiting key oncogenic transcription factors, including p-STAT3, c-Myc and HIF-1 α . These transcription factors are widely sought targets that may also play a role in the inability of immune checkpoint inhibitors to affect more resistant tumors. Moleculin is also developing new prodrugs to exploit the potential uses of inhibitors of glycolysis. The Company's lead Metabolism/Glycosylation Inhibitor compound, WP1122, provides an opportunity to cut off the fuel supply of tumors by taking advantage of their overdependence on glucose as compared with healthy cells. New research also points to the potential for the glucose decoy (2-DG) within WP1122 to be capable of enhancing the usefulness of checkpoint inhibitors.

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 file an IND for WP1732; and the ability of Moleculin's drug candidates to show safety and efficacy in patients. 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

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---Financial tables on the following page---

Moleculin Biotech, Inc.

Unaudited Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2019	December 31, 2018
Current Assets:		
Cash and cash equivalents	\$ 8,782	\$ 7,134
Prepaid expenses and other	831	840
Total current assets	9,613	7,974
Furniture and equipment, net	431	463
Intangible assets	11,148	11,148
Operating lease right-of-use asset	106	—
Total Assets	\$ 21,298	\$ 19,585
Current Liabilities:		
Accounts payable, accrued expenses and current liabilities	\$ 4,050	\$ 3,698
Warrant liability - current	2,386	180
Total current liabilities	6,436	3,878
Operating lease liability - long-term, net of current portion	180	—
Deferred rent - long term	—	107
Warrant liability - long term	—	1,328
Total Liabilities	6,616	5,313
Total Stockholders' Equity	14,682	14,272
Total Liabilities and Stockholders' Equity	\$ 21,298	\$ 19,585

Unaudited Condensed Consolidated Statements of Operations (in thousands, except shares and per share amounts)

	Three Months Ended March 31,	
	2019	2018
Revenues	\$ —	\$ —
Operating Expenses:		
Research and development	2,932	1,237
General and Administrative and depreciation and amortization	1,639	1,400
Total operating expenses	4,571	2,637
Loss from operations	(4,571)	(2,637)
Other income (expense)		
Gain from change in fair value of warrant liability	529	709
Interest income (expense), net	1	1
Net Loss	\$ (4,041)	\$ (1,927)
Net loss per common share - basic and diluted	\$ (0.14)	\$ (0.08)
Weighted average common shares outstanding - basic and diluted	29,064,913	23,331,685