UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2020
or
☐TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number: 001-37758

MOLECULIN BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**47-4671997**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(IRS Employer Identification Number)

5300 Memorial Drive, Suite 950
Houston TX **77007**
(Address of principal executive offices) (Zip Code)

713-300-5160
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Registration S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐
Non-accelerated filer ☒
Accelerated filer ☐
Smaller reporting company ☒
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. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.): Yes ☐ No ☒

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 $0.001 per share	MBRX	The NASDAQ Stock Market LLC

The registrant had 61,704,290 shares of common stock outstanding at August 7, 2020.

Moleculin Biotech, Inc.

Table of Contents

PART 1 FINANCIAL INFORMATION

Item 1. Financial Statements

Moleculin Biotech, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except for share and per share data)
(unaudited)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 16,734	$ 10,735
Prepaid expenses and other current assets	3,015	2,749
Total current assets	19,749	13,484
Furniture and equipment, net	238	316
Intangible assets	11,148	11,148
Operating lease right-of-use asset	245	287
Total assets	$ 31,380	$ 25,235
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,918	$ 2,153
Accrued expenses and other current liabilities	1,821	1,417
Total current liabilities	3,739	3,570
Operating lease liability - long-term, net of current portion	220	276
Warrant liability - long-term	11,792	5,818
Total liabilities	15,751	9,664
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; 100,000,000 shares authorized as of June 30, 2020 and December 31, 2019, 60,403,164 and 45,727,700 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	60	46
Additional paid-in capital	66,428	55,055
Accumulated other comprehensive income	23	31
Accumulated deficit	(50,882)	(39,561)
Total stockholders' equity	15,629	15,571
Total liabilities and stockholders' equity	$ 31,380	$ 25,235

See accompanying notes to unaudited condensed consolidated financial statements.

Moleculin Biotech, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	3,329	2,099	6,535	5,031
General and administrative	1,653	1,484	3,463	3,075
Depreciation and amortization	52	49	98	97
Total operating expenses	5,034	3,632	10,096	8,203
Loss from operations	(5,034)	(3,632)	(10,096)	(8,203)
Other income (loss):				
Gain (loss) from change in fair value of warrant liability	(5,099)	2,407	(1,254)	2,936
Other income, net	17	—	22	—
Interest income, net	4	4	7	5
Net loss	$ (10,112)	$ (1,221)	$ (11,321)	$ (5,262)
Net loss per common share - basic and diluted	$ (0.17)	$ (0.03)	$ (0.21)	$ (0.15)
Weighted average common shares outstanding, basic and diluted	59,483,267	42,393,031	54,707,132	35,765,790
Net Loss	$ (10,112)	$ (1,221)	$ (11,321)	$ (5,262)
Other comprehensive income (loss):				
Foreign currency translation	25	(2)	(8)	(13)
Comprehensive loss	$ (10,087)	$ (1,223)	$ (11,329)	$ (5,275)

See accompanying notes to unaudited condensed consolidated financial statements.

Moleculin Biotech, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (11,321)	$ (5,262)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	98	97
Stock-based compensation	805	666
Change in fair value of warrant liability	1,254	(2,936)
Operating lease, net of sublease receipts	95	(6)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(266)	(667)
Accounts payable	(235)	11
Accrued expenses and other current liabilities	295	(1,097)
Net cash used in operating activities	(9,275)	(9,194)
Cash flows from investing activities:		
Purchase of fixed assets	(20)	(34)
Net cash used in investing activities	(20)	(34)
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	5
Proceeds from exercise of warrants	5	1,557
Proceeds from sale of common stock, net of issuance costs	15,298	19,240
Net cash provided by financing activities	15,303	20,802
Effect of exchange rate changes on cash and cash equivalents	(9)	$ (13)
Net change in cash and cash equivalents	5,999	11,561
Cash and cash equivalents, at beginning of period	10,735	7,134
Cash and cash equivalents, at end of period	$ 16,734	$ 18,695
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ —	$ 1
Cash paid for taxes	$ 15	$ 11
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued liabilities	$ 21	$ 21

See accompanying notes to unaudited condensed consolidated financial statements.

Moleculin Biotech, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except for shares)
(unaudited)

	Six Months Ended June 30, 2020					
	Common Stock					
	Shares	Par Value Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Stockholders' Equity
Balance, December 31, 2019	45,727,700	$ 46	$ 55,055	$ (39,561)	$ 31	$ 15,571
Issued for cash - sale of common stock, net of issuance costs of $709	7,500,000	7	559	—	—	566
Stock-based compensation	—	—	397	—	—	397
Consolidated net loss	—	—	—	(1,209)	—	(1,209)
Cumulative translation adjustment	—	—	—	—	(33)	(33)
Balance, March 31, 2020	53,227,700	$ 53	$ 56,011	$ (40,770)	$ (2)	$ 15,292
Issued for cash - sale of common stock, net of issuance costs of $336	7,170,964	7	10,000	—	—	10,007
Warrants exercised	4,500	—	9	—	—	9
Stock-based compensation	—	—	408	—	—	408
Consolidated net loss	—	—	—	(10,112)	—	(10,112)
Cumulative translation adjustment	—	—	—	—	25	25
Balance, June 30, 2020	60,403,164	$ 60	$ 66,428	$ (50,882)	$ 23	$ 15,629

	Six Months Ended June 30, 2019					
	Common Stock					
	Shares	Par Value Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Stockholders' Equity
Balance, December 31, 2018	28,528,663	$ 29	$ 40,564	$ (26,356)	$ 35	$ 14,272
Issued for cash - sale of common stock, net of issuance costs of $617	5,250,000	5	3,221	—	—	3,226
Issued to Lincoln Park - sale of common stock	605,367	—	883	—	—	883
Stock options exercised	25,000	—	5	—	—	5
Stock-based compensation	—	—	348	—	—	348
Consolidated net loss	—	—	—	(4,041)	—	(4,041)
Cumulative translation adjustment	—	—	—	—	(11)	(11)
Balance, March 31, 2019	34,409,030	$ 34	$ 45,021	$ (30,397)	$ 24	$ 14,682
Issued for cash - sale of common stock, net of issuance costs of $302	9,375,000	9	3,575	—	—	3,584
Warrants exercised	1,413,018	2	4,729	—	—	4,731
Stock-based compensation	—	—	318	—	—	318
Consolidated net loss	—	—	—	(1,221)	—	(1,221)
Cumulative translation adjustment	—	—	—	—	(2)	(2)
Balance, June 30, 2019	45,197,048	$ 45	$ 53,643	$ (31,618)	$ 22	$ 22,092

See accompanying notes to unaudited condensed consolidated financial statements.

Moleculin Biotech, Inc.
Notes to the Unaudited Condensed Consolidated Financial Statements

1. Nature of Business and Liquidity

The terms "MBI" or "the Company", "we", "our", and "us" are used herein to refer to Moleculin Biotech, Inc. MBI is a clinical-stage pharmaceutical company, organized as a Delaware corporation in July 2015, with its focus on the treatment of highly resistant cancers and viruses via the development of its drug candidates, all of which are based on license agreements with The University of Texas System on behalf of the MD Anderson Cancer Center, which we refer to as MD Anderson. MBI formed Moleculin Australia Pty. Ltd., (MAPL), a wholly owned subsidiary, to perform certain preclinical development in Australia. This enables the Company to enjoy the benefits of certain research and development tax credits in Australia. In February 2019, the Company entered into an agreement with Animal Life Sciences, LLC (ALI), where the Company has granted a sublicense to ALI to research, develop, make, have made, use, offer to sell, sell, export or import and commercialize certain licensed products for non-human use and share development data. ALI issued to the Company a 10% interest in ALI. ALI converted into a corporation and became Animal Life Sciences, Inc.

Core Technologies - MBI has three core technologies, two of which have multiple drug candidates, and all of which are based on discoveries made at MD Anderson. These core technologies are 1) Annamycin, 2) its STAT3 Immune/Transcription Modulators, or simply "Immune/Transcription Modulators" WP1066 portfolio and 3) its Antimetabolite (including Metabolism/Glycosylation Inhibitors) WP1122 portfolio of molecules. The Company's clinical stage drugs are Annamycin, an anthracycline which is in two Phase 1/2 studies for the treatment of relapsed acute myeloid leukemia, (AML), WP1066, an Immune/Transcription Modulator, which is in two Phase 1 clinical trials in the United States of America (US) for the treatment of brain tumors, and WP1220, a member of the WP1066 portfolio of drugs, which has completed a Phase 1 proof-of-concept clinical trial for the topical treatment of cutaneous T-cell lymphoma (CTCL), a form of skin cancer.

The Company refers to Annamycin as a "Next Generation Anthracycline" since it is designed to avoid the multidrug resistance mechanisms that typically defeat currently approved anthracyclines, as well as to be non-cardiotoxic, which is the dose limiting toxicity for all currently approved anthracyclines. Annamycin is currently in a Phase 1/2 clinical trial in Europe, having successfully completed a Phase 1 safety trial in the US in 2019, and preliminary clinical data suggests that it may have the potential to become the first therapy suitable for the majority of relapsed AML patients regardless of gene mutations. These trials have so far demonstrated safety, including the absence of any cardiotoxicity, and have demonstrated some initial efficacy despite the fact that the Company considers testing so far to have been at substantially sub-therapeutic doses. Additionally, preclinical research in animal models at MD Anderson demonstrated that Annamycin is able to significantly improve survival in an aggressive form of triple negative breast cancer metastasized to the lungs. Coupled with research demonstrating that Annamycin is capable of accumulating in the lungs at high levels, this suggests that Annamycin may be well suited to become a treatment for lung-localized tumors and the Company is performing preclinical work to enable an IND or its equivalent to be filed this year.

WP1066 is one of several Immune/Transcription Modulators in the Company's pipeline that appear 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-1α. These transcription factors are widely sought targets that may also play a role in the lack of efficacy of immune checkpoint inhibitors in certain resistant tumors. The "proof-of-concept" Phase 1 trial in Poland for WP1220 demonstrated safety and efficacy and the Company intends to file a Phase 2 IND or its equivalent or to attempt to join efforts with a strategic partner for the continued development of WP1220 as a topical therapy for CTCL.

The Company is also developing new prodrugs to exploit the potential uses of its WP1122 portfolio of antimetabolites, including inhibitors of glycolysis and glycosylation. Its lead Metabolism/Glycosylation Inhibitor compound, WP1122, provides an opportunity to cut off the fuel supply of tumors and viruses by taking advantage of their overdependence on glucose and glycolysis 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 and inhibiting glycosylation and glycolysis in virally infected cells. During the first half of 2020, the Company entered into agreements with several outside research centers to conduct research on WP1122 for antiviral properties against a range of viruses, including Coronavirus. Additional research with other molecules in this portfolio with independent contractors has also begun.

Drug Candidates - Within the Company's core technologies, it currently has five drug candidates representing three substantially different mechanisms of action. Annamycin is a chemotherapy designed to inhibit the replication of DNA of rapidly dividing cells and is the Company's most mature drug candidate. The Company has a trial open in Poland and one that recently completed in the US. The US Phase 1 portion of the Phase 1/2 trial reached key safety end points in early 2020. As a result of discussions with the FDA, the Company will utilize its trial in Europe to establish a recommended Phase 2 dose (RP2D) and to generate additional safety and efficacy data as requested by the FDA. The Phase 1/2 trial in Poland continues its dose escalation and is in its fifth cohort. So far both trials have demonstrated that Annamycin, to date, is safe and is non-cardiotoxic. The trials have demonstrated initial efficacy as well.

In addition to Annamycin, the Company has other drug development projects, two of which are also in clinical trials:

- Two separate Phase 1 physician-sponsored clinical trials are under way to evaluate WP1066. One trial is at MD Anderson Cancer Center for the potential treatment of adult patients with brain tumors and the other is at Emory University for the potential treatment of pediatric brain tumors. Both have begun treating patients.

- The Company is also evaluating WP1066 for the potential treatment of AML and pancreatic and other cancers. MBI has begun pre-clinical work that it expects to generate sufficient data for an IND for an intravenous formulation of one of its STAT3 inhibitors, which filing is expected to be submitted in 2021.

- WP1220 is an analog of WP1066 for which Polish authorities approved the Company's Clinical Trial Application (CTA) in 2019 for a Phase 1 "proof-of-concept" clinical trial to study the topical treatment of CTCL. This trial was completed, and the Company believes it demonstrated sufficient efficacy to justify a Phase 2 trial. The Company intends to file a Phase 2 IND or its equivalent or to attempt to join efforts with a strategic partner in 2021 for the further development of WP1220 for the treatment of CTCL.

- Several molecules in the WP1122 portfolio are being evaluated for their potential to address hard to treat cancers and viruses. This portfolio of antimetabolites includes WP1122 which inhibits glycolysis and glycosylation. The Company has begun preclinical work on WP1122 and other analogs in this portfolio to position one or more of them as treatments for certain cancers and viruses, including the Coronavirus. The Company believes this work may support an IND or its equivalent for WP1122 and/or related compounds.

Clinical Trials - The Company has concluded the initial Phase 1 portion of its Phase 1/2 trial of Annamycin for the potential treatment of AML in the US due to the FDA’s requirement to set the initial dose level relatively low in comparison with previous Annamycin clinical trials. Additionally, the Company believes that patient recruitment for its Annamycin AML clinical trial in Europe will continue to be more successful than in the US due to a comparatively lower number of competitive clinical trials and the protocol there being approved to start at a significantly higher dose than in the US with fewer enrollment screening limitations. This European AML trial is in its fifth cohort in the dose ranging Phase 1 portion of the trial. The Company has also announced plans to submit an IND or its equivalent for the use of Annamycin to potentially treat lung metastases, which it expects to submit before the end of 2020.

In September 2018, the physician-sponsored WP1066 Phase 1 clinical trial for the treatment of glioblastoma and melanoma metastasized to the brain, which opened for recruitment in July 2018, began treating patients. In April 2020, a second physician-sponsored Phase 1 trial for the potential treatment of pediatric brain tumors began recruitment and has treated its first patient. In August 2019, the Company completed its proof-of-concept Phase 1 clinical trial in Poland to study WP1220, a part of the WP1066 portfolio, for the treatment of CTCL. This trial demonstrated the safety of WP1220 and also demonstrated, the Company believes, initial efficacy sufficient for a Phase 2 trial. The Company intends to file a Phase 2 IND or its equivalent or to attempt to join efforts with a strategic partner in 2021 for the further development of WP1220 for the treatment of CTCL.

Moleculin has recently announced discoveries (both internally funded and independently developed) supporting the potential use of WP1122 for the treatment of COVID-19 and other viral diseases. The Company is focusing resources on the development of an IND or its equivalent for testing WP1122 in COVID-19 patients, which it expects to submit before the end of 2020.

Licenses - The Company has been granted royalty-bearing, worldwide, exclusive licenses for the patent and technology rights related to all of MBI's drug technologies, as these intellectual property rights are owned in part or entirely by MD Anderson. The Annamycin drug substance is no longer covered by any existing patent protection, however, the Company filed new patent applications in July 2019 for formulation, synthetic process and reconstitution related to MBI's Annamycin

drug product candidate, although there is no assurance that the Company will be successful in obtaining such patent protection. Such technology is also licensed from MD Anderson. The Company sponsors significant research at MD Anderson. New patents may result out of this research. From time to time, there are license issues that need to be discussed and handled with MD Anderson such as adding additional patents to existing license agreements and extension of milestones. The Company believes that such issues will be handled in the ordinary course of business.

On May 20, 2020, the Company entered into an amendment (Amendment) to the Patent and Technology License Agreement dated April 2, 2012 entered into by and between Intertech Bio Corporation and The Board of Regents (Board) of The University of Texas System on behalf of The University of Texas M. D. Anderson Cancer Center (UTMDACC), as previously amended on October 19, 2015 (Amendment 1) and November 1, 2018 (Amendment 2) and collectively, the (WP122 Agreement). The WP1122 Agreement was assigned to the Company on November 17, 2015. Pursuant to the WP1122 Agreement, the Company obtained a royalty-bearing, worldwide, exclusive license to intellectual property, including patent rights, related to its WP1122 portfolio and to the drug product candidate, WP1122. In consideration, the Company must make payments to UTMDACC including an up-front payment, license documentation fee, annual maintenance fee, milestone payments and minimum annual royalty payments for sales of products developed under the WP1122 Agreement. Pursuant to the WP1122 Agreement, the Board and UTMDACC have the right to terminate the WP1122 Agreement if the Company does not, within certain time periods: (i) file an Investigational New Drug Application with the FDA for a Phase I Study for a Licensed Product ("IND filing requirement"); and (ii) commence a Phase I Study for a Licensed Product (Phase I study requirement). Pursuant to the Amendment, the Company is required to meet the IND filing requirement within nine months of the date of the Amendment (the previous requirement was three years from the date of Amendment 1 and 18 months from the date of Amendment 2) and the Phase I study requirement within 2.5 years of the date of the Amendment (the previous requirement was five years from the date of Amendment 1 and 3.5 years from the date of Amendment 2); provided the Company has the right to extend such time periods for up to an additional 18 months by the payment of certain extension payments to UTMDACC.

Independently from potential patent protection, MBI has received Orphan Drug designation (ODD) from the FDA for Annamycin for the treatment of AML and for WP1066 for the treatment of glioblastoma. ODD may provide tax and other benefits during product development, and if either product is approved, may lead to a grant of seven-year market exclusivity. Under that exclusivity, which runs from the date of the approval of the New Drug Application (NDA) in the US, the FDA generally (there are important exceptions) could not approve another product containing the same drug for the designated indication. The Company also intends to apply for similar status in the European Union (EU) where market exclusivity could extend to 10 years from the date of Marketing Authorization Application (MAA) approval. Separately, the FDA may also grant market exclusivity of 5 years for newly approved new chemical entities (which the Company believes Annamycin would be one), which would preclude approval of any other annamycin product, but there can be no assurance that such exclusivity will be granted. In April 2019, FDA approved the Company's request for Fast Track Designation for Annamycin for the treatment of relapsed or refractory AML. Fast Track Designation, the purpose of which is to expedite drug development and approval, is granted to drugs intended to treat serious conditions and where data demonstrate the potential to address an unmet medical need.

COVID 19 - In March 2020, the World Health Organization declared the outbreak of a novel Coronavirus (COVID-19) as a pandemic, which continues to spread throughout the US. The spread of COVID-19 has caused significant volatility in US and international markets, including Poland, where the Company conducts some of its clinical trials and Italy, where its drug supply is produced. There has been limited interruption of the Company’s drug supply, and some Polish clinics where the Company is conducting trials have limited access on monitoring activities, which for now has not materially slowed the progress of the Company's trials. This could change at any time. Furthermore, there is significant uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the US and international economies and, as such, the Company is unable to determine if it will have a material impact to its operations.

Nasdaq - On April 23, 2020, the Company received a letter from NASDAQ notifying the Company that it had regained compliance with NASDAQ Listing Rule 5550(a)(2) as a result of the closing bid price of the Company's common stock being at $1.00 per share or greater for the 10 consecutive business days from April 8, 2020 through April 22, 2020. Accordingly, the Company is in compliance with the Bid Price Rule and NASDAQ considers the matter closed.

2. Basis of presentation, principles of consolidation and significant accounting policies

Basis of Presentation – Unaudited Interim Condensed Consolidated Financial Information - The accompanying unaudited interim condensed consolidated financial statements and related notes have been prepared in accordance with

accounting principles generally accepted in the US (U.S. GAAP) for financial information, and in accordance with the rules and regulations of the US Securities and Exchange Commission (SEC) with respect to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim condensed consolidated financial statements furnished reflect all adjustments (consisting of normal recurring adjustments), which are, in the opinion of management, necessary for a fair statement of results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. These interim condensed unaudited consolidated financial statements should be read in conjunction with the audited financial statements of the Company as of December 31, 2019 and December 31, 2018 and notes thereto contained in the Form 10-K filed with the SEC on March 19, 2020.

Principles of consolidation - The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP. The company views its operations and manages its business in one operating segment. All long-lived assets of the Company reside in the US.

Use of Estimates - The preparation of these condensed consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of financial statements. Estimates are used in the following areas, among others: fair value estimates on intangible assets, warrants, and stock-based compensation expense, as well as accrued expenses and taxes.

Going Concern - These condensed consolidated financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The continuation of the Company as a going concern is dependent upon the ability of the Company to obtain necessary equity financing to continue operations and the attainment of profitable operations. As of June 30, 2020, the Company has incurred an accumulated deficit of $50.9 million since inception and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of June 30, 2020, is sufficient to fund its planned operations into but not beyond the near term. These factors raise substantial doubt regarding the Company’s ability to continue as a going concern. These unaudited condensed consolidated financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements and delay planned cash outlays or a combination thereof. Management cannot be certain that such events or a combination thereof can be achieved.

On May 1, 2020, the Securities and Exchange Commission (SEC) announced a temporary suspension of trading in the Company's securities due to questions regarding the accuracy and adequacy of information in the marketplace about the Company and its securities, related to, among other things, statements made by the Company and others, in the Company's Form 10-K filed March 19, 2020, in press releases on March 20, 2020 and April 8, 2020 and in other statements on March 19, 2020; March 20, 2020; and April 16, 2020 concerning the Company's business, including the status of development of a drug candidate labeled WP1122 for potential application to COVID-19, and the Company's ability to expedite regulatory approval of any such treatment. Pursuant to the suspension order, the trading halt was initiated at 9:30 a.m. EDT on May 4, 2020 and terminated at 11:59 p.m. EDT on May 15, 2020. Commencing May 18, 2020, the Nasdaq Stock Market placed a halt on the trading of the Company's common stock pending the receipt of additional information, which the Company provided. This halt was lifted on May 28, 2020. The Company believes in the accuracy and adequacy of its public disclosures but can provide no assurances that it will not encounter future similar actions, which may adversely affect the holders of the Company's common stock.

Cash and Cash Equivalents - The Company considers all highly liquid accounts with original maturities of three months or less at the date of acquisition to be cash equivalents. Periodically in the ordinary course of business, the Company may carry cash balances at financial institutions in excess of the Federally insured limits of $250,000.

Prepaid Expenses and Other Current Assets - Prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2020	December 31, 2019
Vendor prepayments and deposits	$ 1,352	$ 1,857
Prepaid insurance	1,214	352
Related party receivables	10	10
Non-trade receivables	3	1
Other current assets	436	529
Total prepaid expenses and other current assets	$ 3,015	$ 2,749

Vendor prepayments at June 30, 2020 and December 31, 2019, respectively, includes approximately $1.1 million and $1.5 million, for the expansion of Annamycin production commitments on a commercial scale currently expected to be delivered in 2020 for use in clinical trials.

Intangible Assets - Intangible assets with finite lives are amortized using the straight-line method over their estimated period of benefit. Acquired intangible assets identified as in-process research and development (IPR&D) assets, are considered indefinite lived until the completion or abandonment of the associated research and development efforts. If the associated research and development effort is abandoned, the related IPR&D assets will be written-off and the Company will record a noncash impairment loss on its statements of operations. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives. The Company evaluates the recoverability of intangible assets periodically and take into account events or circumstances that warrant revised estimates of useful lives or that indicate that impairment exists. No impairments of intangible assets have been identified during any of the periods presented. Intangible assets are tested for impairment on an annual basis, and between annual tests if indicators of potential impairment exist, using a fair-value-based approach.

Property and Equipment, net - Leasehold improvements, furniture, equipment and software are recorded at cost and are depreciated using the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the shorter of the estimated useful life or the remaining lease term. Accumulated depreciation on property and equipment was $0.4 million and $0.3 million at June 30, 2020 and December 31, 2019, respectively.

Operating Lease Right-of-Use Asset - The Company determines if an arrangement is a lease at contract inception or during modifications or renewal of an existing lease. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. The lease payments used to determine the Company's operating lease assets may include lease incentives, stated rent increases and escalation clauses linked to rates of inflation when determinable and are recognized in the Company's operating lease assets in the Company's condensed consolidated balance sheet. The Company has elected the practical expedient and does not separate lease components from nonlease components for its leases. The Company's operating leases are reflected in operating lease right-of-use asset (ROU), accrued expenses and other current liabilities, and operating lease liability - long-term, net of current portion in the Company's condensed consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Short-term leases, defined as leases that have a lease term of 12 months or less at the commencement date, are excluded from this treatment and are recognized on a straight-line basis over the term of the lease. Refer to Note 7 - Commitments and Contingencies - Lease Obligations Payable for additional information related to the Company’s operating leases.

Cost Method Investment - The Company's cost method investment consists of an investment in a corporation in which it does not have the ability to exercise significant influence over its operating and financial activities. Management evaluates this investment for possible impairment quarterly.

Fair Value of Financial Instruments - The Company's financial instruments consist primarily of non-trade receivables, accounts payable, accrued expenses and its warrant liability. The carrying amount of non-trade receivables, accounts payable, and accrued expenses approximates their fair value because of the short-term maturity of such.

The Company has categorized its assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy in accordance with U.S. GAAP. Fair value is defined as the exchange price that would be received for

an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3).

Assets and liabilities recorded in the balance sheets at fair value are categorized based on a hierarchy of inputs as follows:

Level 1 – Unadjusted quoted prices in active markets of identical assets or liabilities.
Level 2 – Quoted prices for similar assets or liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument.
Level 3 – Unobservable inputs for the asset or liability.

The Company's financial assets and liabilities recorded at fair value on a recurring basis include the fair value of warrant liability discussed in Note 4.

The following table provides assets and liabilities reported at fair value and measured on a recurring basis at June 30, 2020 and December 31, 2019 (in thousands):

Description	Liabilities Measured at Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Fair value of warrant liability as of June 30, 2020:	$ 11,792	$ —	$ —	$ 11,792
Fair value of warrant liability as of December 31, 2019:	$ 5,818	$ —	$ —	$ 5,818

The table below (in thousands) of Level 3 liabilities begins with the valuation as of the beginning of the second quarter and then is adjusted for the issuances and exercises that occurred during the second quarter of 2020 and adjusts for balances for changes in fair value that occurred during the current quarter. The ending balance of the Level 3 financial instrument presented above represents our best estimates and may not be substantiated by comparison to independent markets and, in many cases, could not be realized in immediate settlement of the instruments.

Three Months Ended June 30, 2020	Warrant Liability Current	Warrant Liability Long-Term	Warrant Liability Total
Balance, March 31, 2020	$ —	$ 6,697	$ 6,697
Exercise of warrants	—	(4)	(4)
Change in fair value - net	—	5,099	5,099
Balance, June 30, 2020	$ —	$ 11,792	$ 11,792

The table below (in thousands) of Level 3 liabilities begins with the valuation as of December 31, 2019 and then is adjusted for the issuances and exercises, and changes in fair value that occurred during the six months ended June 30, 2020. The ending balance of the Level 3 financial instrument presented above represents our best estimates and may not be substantiated by comparison to independent markets and, in many cases, could not be realized in immediate settlement of the instruments.

Six Months Ended June 30, 2020	Warrant Liability Current	Warrant Liability Long-Term	Warrant Liability Total
Balance, December 31, 2019	$ —	$ 5,818	$ 5,818
Issuances of warrants	—	4,724	4,724
Exercise of warrants	—	(4)	(4)
Change in fair value - net	—	1,254	1,254
Balance, June 30, 2020	$ —	$ 11,792	$ 11,792

Loss Per Common Share - Basic net loss per common share is computed by dividing net loss available to common shareholders by the weighted-average number of common shares outstanding during the period. For purposes of this calculation, options to purchase common stock, restricted stock units subject to vesting and warrants to purchase common stock are considered to be common stock equivalents. Diluted net loss per common share is determined using the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents. In periods when losses are reported, the weighted-average number of common shares outstanding excludes common stock equivalents, because their inclusion would be antidilutive. For the three months ended June 30, 2020 and 2019, approximately 21.2 million and approximately 12.3 million, respectively, of potentially dilutive shares were excluded from the computation of diluted earnings per share due to their antidilutive effect. For the six months ended June 30, 2020 and 2019, approximately 19.8 million and approximately 9.5 million, respectively, of potentially dilutive shares were excluded from the computation of diluted earnings per share due to their antidilutive effect.

Stock-based Compensation - Stock-based compensation expense includes the estimated fair value of equity awards vested or expected to vest during the reporting period. The Company accounts for its stock-based compensation awards in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification Topic (ASC) 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, restricted stock units, and modifications to existing stock options, to be recognized in the consolidated statements of operations based on their fair values. The grant date fair value of stock options is determined using the Black-Scholes option pricing model and the grant date fair value of restricted stock awards is determined using the closing price of the Company's common stock on the date of grant (or if the date of grant is not a business day, on the business day prior to the date of the grant). The awards are subject to service vesting conditions. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term, net of forfeitures which are recognized as they occur. Compensation expense related to awards to non-employees with service-based vesting conditions is recognized based on the then-current fair value at each financial reporting date prior to the measurement date over the associated service period of the award or the vesting event, applicable, which is generally the vesting term. Effective January 1, 2020, the Company began using the volatility of its own stock since it now has sufficient historic data in its stock price.

Subsequent Events - The Company's management reviewed all material events through the date these unaudited condensed consolidated financial statements were issued for subsequent events disclosure consideration, see other notes and specifically Note 8 - Subsequent Events.

Recent Accounting Pronouncements

In August 2018, the FASB issued Accounting Standards Update (ASU) No. 2018-13, Fair Value Measurement (Topic 820) (ASU 2018-13). ASU 2018-13 modifies the disclosure requirements on fair value measurements in ASC Topic 820, Fair Value Measurement, based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company's adoption of this pronouncement effective January 1, 2020 did not have a material impact on the Company's condensed consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740) (ASU 2019-12). ASU 2019-12 modifies the requirements for the timing of adoption of enacted change in tax law. The effects of changes on taxes currently payable or refundable for the current year must be reflected in the computation of annual effective tax rate in the first interim period that includes the enactment date of the new legislation, beginning after December 15, 2020. Early adoption is permitted upon issuance of this ASU. The Company is currently evaluating the impact that this standard will have, if any, on its financial statements.

The Company does not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying condensed consolidated financial statements.

3. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following components (in thousands):

	June 30, 2020	December 31, 2019
Accrued payroll and bonuses	$ 800	$ 436
Accrued drug manufacturing costs	349	49
Accrued legal, regulatory and professional fees	220	272
Accrued clinical testing	135	93
Operating lease liability - current	110	103
Related party payable	99	99
Accrued other	75	164
Accrued license fees and sponsored research agreements	33	201
Total accrued expenses and other current liabilities	$ 1,821	$ 1,417

4. Warrants

At June 30, 2020, and December 31, 2019, respectively, the Company has the following warrants outstanding:

	Number of Shares Under Outstanding Warrants at June 30, 2020	Number of Shares Under Outstanding Warrants at December 31, 2019	Weighted Average Exercise Price at June 30, 2020	Remaining Contractual Life at June 30, 2020 (No. Years)
Liability Classified Warrants [1]				
Issued February 2017	404,002	404,002	$ 1.50	1.6
Issued February 2018	2,273,700	2,273,700	2.80	3.1
Issued June 2018 [2]	742,991	742,991	2.03	3.4
Issued March 2019	1,581,000	1,585,500	1.10	3.8
Issued April 2019	5,250,000	5,250,000	1.75	3.8
Issued February 2020	6,150,000	—	1.05	5.1
	16,401,693	10,256,193	$ 1.58	
Equity Classified Warrants				
Issued May 2016 - Bonwick	107,802	107,802	$ 7.50	0.8
Issued July 2017 - Consulting [3]	150,000	150,000	2.61	2.1
Issued April 2018 - Consulting	100,000	100,000	3.00	0.8
Issued August 2019 - Consulting	150,000	150,000	1.64	2.1
Issued April 2020 - Consulting	100,000	—	1.14	4.8
	607,802	507,802	$ 3.06	
Balance outstanding	17,009,495	10,763,995	$ 1.63	

[1] If the Company subdivides (by any stock split, stock dividend, recapitalization or otherwise) its outstanding shares of its common stock into a smaller number of shares, the warrant exercise price is proportionately reduced and the number of shares under outstanding warrants is proportionately increased. Additionally, if the Company combines (by combination, reverse stock split or otherwise) its outstanding shares of common stock into a smaller number of shares, the warrant exercise price is proportionately increased and the number of shares under outstanding warrants is proportionately decreased. Also, the Company may voluntarily reduce the warrant exercise price for its warrants issued in March 2019 and February 2017 and may voluntarily extend the contractual term of its warrants issued in February 2017.

[2] Includes warrants to purchase 710,212 shares at an exercise price of $2.02, expiring December 22, 2023, and warrants to purchase 32,779 shares at an exercise price of $2.32, expiring June 21, 2023.

[3] Includes warrants to purchase 100,000 shares at an exercise price of $2.41 and warrants to purchase 50,000 shares at an exercise price of $3.00.

Liability Classified Warrants

The Company uses the Black-Scholes option pricing model (BSM) to determine the fair value of its warrants at the date of issue and outstanding at each reporting date.

The risk-free interest rate assumption is based upon observed interest rates on zero coupon US Treasury bonds linearly interpolated to obtain a maturity period commensurate with the term of the warrants.

Estimated volatility is a measure of the amount by which the Company's stock price is expected to fluctuate each year during the expected life of the warrants. Beginning in 2020, only the volatility of the Company's own stock is used in the BSM as it now has sufficient historic data in its stock price. In 2019, the Company used the volatility of its own stock blended with the volatility of peer entities due to the lack of sufficient historical data of its stock price.

The assumptions used in determining the fair value of the Company's outstanding liability classified warrants are as follows:

	June 30, 2020			December 31, 2019		
Risk-free interest rate	0.2 %	to	0.4 %	1.6 %	to	1.7 %
Volatility	121.3 %	to	144.8 %	97.5 %	to	107.5 %
Expected life (years)	1.6	to	5.1	2.1	to	4.3
Dividend yield	—%			—%		

A summary of the Company's liability classified warrant activity during the six months ended June 30, 2020 and related information follows:

	Number of Shares Under Warrant	Range of Warrant Exercise Price per Share		Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Balance at January 1, 2020	10,256,193	$ 1.10	$ 2.80	$ 1.89	4.0
Granted	6,150,000	1.05	1.05	1.05	5.1
Exercised	(4,500)	1.10	1.10	1.10	—
Expired	—	—	—	—	—
Balance at June 30, 2020	16,401,693	$ 1.05	$ 2.80	$ 1.58	4.1
Vested and Exercisable at June 30, 2020	10,251,693	$ 1.10	$ 2.80	$ 1.89	3.5

In connection with the Company's stock offering that closed on February 10, 2020, the Company issued warrants to purchase 5,625,000 shares of its common stock, that are exercisable six months from the date of issuance, at a price of $1.05 per share, subject to adjustment in certain circumstances, and expire five years from the date they are first exercisable, and issued Oppenheimer & Co. Inc. a warrant (Underwriter Warrant) to purchase up to 525,000 shares of its common stock with an exercise price of $1.05 per share, subject to adjustment in certain circumstances, which expires on February 6, 2025.

For a summary of the changes in fair value associated with our warrant liability for the six months ended June 30, 2020, see Note 2 - Basis of presentation, principles of consolidation and significant accounting policies - Fair Value of Financial Instruments.

Equity Classified Warrants

In April 2020, equity warrants to purchase up to 100,000 shares of common stock were issued to a consultant, with vesting contingent on certain conditions focused on generating up to $10 million of approved research and development expenditures on the Company's drug portfolio.

At June 30, 2020 the Company had 607,802 equity classified warrants outstanding and 512,802 warrants were exercisable. At December 31, 2019, the Company had 507,802 equity classified warrants outstanding and all were exercisable.

The Company recorded stock compensation expense for non-employee consulting agreements of $5,000 and zero for the three months ended June 30, 2020 and 2019, respectively, and $5,000 and $2,000 during the six months ended June 30, 2020 and 2019, respectively. At June 30, 2020, there was $91,000 of unrecognized stock compensation expense related to the Company's equity-classified warrants.

5. Equity

April 2020 Stock Issuances

In April 2020, pursuant to the 2019 ATM Agreement, the Company issued 7,170,964 shares of common stock at an average price of $1.44 per share through the ATM Prospectus Supplement. The Company received total proceeds of $10.3 million, net of $0.3 million in transaction expenses.

February 2020 Stock Offering

In February 2020, the Company entered into subscription agreements with certain institutional investors for the sale by the Company of 7,500,000 shares of its common stock and warrants to purchase 5,625,000 shares of common stock at a combined public offering price of $0.80 per share and related warrant. The Company received total proceeds of $6.0 million, net of $0.7 million in transaction expenses. See Note 4 - Warrants for equity classified warrants granted during the six months ended June 30, 2020.

Stock-based Compensation and Outstanding Awards

Under the terms of the Company’s 2015 Stock Plan, as amended, and approved by its stockholders on June 15, 2020, 10.5 million shares of the Company’s common stock were available for grant to employees, non-employee directors and consultants. The 2015 Stock Plan provides for the grant of stock options, stock awards, stock unit awards, or stock appreciation rights. As of June 30, 2020, there were 6,227,093 shares remaining to be issued under the 2015 Stock Plan.

Stock-based compensation for the three and six months ended June 30, 2020 and 2019, are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
General and administrative	$ 329	$ 271	$ 664	$ 573
Research and development	79	47	141	93
Total	$ 408	$ 318	$ 805	$ 666

Each of the Company's stock-based compensation arrangements are discussed below.

Stock Options

Stock option awards are generally granted with an exercise price equal to the market price of the Company’s stock at the date of grant. Stock option awards generally have a 10-year contractual term and vest over a 4-year period for employees and over a 1 to 3-year period for directors from the grant date on a straight-line basis over the requisite service period. The grant-date fair value of stock options is determined using the Black-Scholes option-pricing model. Additionally, the Company’s stock options provide for full vesting of unvested outstanding options, in the event of a change of control of the Company.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted below. The expected term of the stock option awards was computed using the “plain vanilla” method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin 107 because the Company does not have sufficient data regarding employee exercise behavior to estimate the expected term. Beginning in 2020, the Company used the volatility of its own stock in the BSM as it now has sufficient historic data in its stock price. Prior to 2020, the volatility was determined by referring to the average historical volatility of a peer group of public companies combined with its

own due to the lack of sufficient historical data of its stock price. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

The fair value of the option grants has been estimated, with the following weighted-average assumptions:

	Six Months Ended June 30,					
	2020			2019		
Risk-free interest rate	0.28%	to	0.46 %	0.95%	to	2.24 %
Volatility	126.40%	to	127.98 %	70.18%	to	89.11 %
Expected life (years)	3.75	to	6.25	5	to	6.25
Expected dividend yield		—%			—%	

Stock option activity for the six months ended June 30, 2020 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2019	3,836,000	$ 1.59	$ 2.26	8.3	$ —
Granted	90,000	$ 1.06	$ 1.24		
Exercised	—	$ —	$ —		
Forfeited	(20,000)	$ 0.89	$ 1.06		
Outstanding, June 30, 2020	3,906,000	$ 1.58	$ 2.24	7.8	$ —
Exercisable, June 30, 2020	1,548,503	$ 1.95	$ 2.89	7.2	$ —

Options granted during 2020 have an aggregated fair value of $0.1 million that was calculated using the Black-Scholes option-pricing model. At June 30, 2020, total compensation cost not yet recognized was $2.2 million and the weighted average period over which this amount is expected to be recognized is 2.13 years. The aggregate fair value of options vesting in the six months ended June 30, 2020 and 2019, respectively, was $0.4 million and $0.5 million, respectively. In July 2020, the Company granted 1,349,750 employee stock options.

Restricted Stock

In July 2019, the Company granted 316,907 restricted stock units, which vest annually in four equal installments. The weighted average grant date fair value of $1.31 per unit was determined using the closing price of the Company's common stock on the grant date. Additionally, the Company's restricted stock unit agreements provide for full vesting of the restricted stock award in the event of a change of control of the Company. During the six months ended June 30, 2020, no restricted stock units vested or were forfeited. As of June 30, 2020, total compensation cost not yet recognized was $0.3 million and the weighted average period over which this amount is expected to be recognized is 3.0 years. In July 2020, the Company granted 353,211 restricted stock units, which vest annually in four equal installments, and 79,227 restricted stock units vested.

6. Income Taxes

Deferred income tax assets and liabilities are determined based upon differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company does not expect to pay any significant federal, state, or foreign income taxes in 2020 as a result of the losses recorded during the three and six months ended June 30, 2020 and the additional losses expected for the remainder of 2020 and cumulative net operating loss carryforwards. Accounting standards require the consideration of a valuation allowance for deferred tax assets if it is "more likely than not" that some component or all of the benefits of deferred tax assets will not be realized. As a result, as of June 30, 2020, the Company maintained a full valuation allowance for all deferred tax assets.

The Company recorded no income tax provision for the three and six months ended June 30, 2020 and 2019, respectively. The effective tax rate for the three and six months ended June 30, 2020 and 2019 is 0%. The income tax rates vary from the federal and state statutory rates primarily due to the change in fair value of the stock warrants and valuation allowances on the Company's deferred tax assets. The Company estimates its annual effective tax rate at the end of each quarterly period. Jurisdictions with a projected loss for the year where no tax benefit can be recognized due to the valuation allowance could result in a higher or lower effective tax rate during a particular quarter depending on the mix and timing of actual earnings versus annual projections.

On March 27, 2020, Congress enacted the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) to provide certain relief as a result of the COVID-19 pandemic. The CARES Act, among other things, includes provisions relating to net operating loss carry back periods, alternative minimum tax credit refunds, and modification to the net interest deduction limitations. The CARES Act did not have a material impact on the Company's condensed consolidated financial statements for the six months ended June 30, 2020. The Company continues to monitor any effects that may result from the CARES Act.

7. Commitments and Contingencies

In addition to the commitments and contingencies described elsewhere in these notes, see below for a discussion of the Company's commitments and contingencies as of June 30, 2020.

Lease Obligations Payable

During the six months ended June 30, 2020, the Company did not enter into any lease arrangements requiring any additional right-of-use assets or liabilities to be recorded.

The following summarizes quantitative information about the Company's operating leases for the three and six months ended June 30, 2020 and 2019, respectively (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Lease cost:				
Operating lease cost	$ 29	$ 8	$ 58	$ 16
Short-term lease cost	4	12	9	26
Variable lease cost	7	7	14	12
Total	$ 40	$ 27	$ 81	$ 54

The Company recorded approximately $10,000 and $21,000 in sublease income from a related party for the three and six months ended June 30, 2020, respectively. Sublease income is recorded as other income, net on the Company's condensed consolidated statement of operations and comprehensive loss.

Other supplemental cash flow information for operating leases is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	$ 33	$ 13	$ 66	$ 21
Right-of-use assets obtained in exchange for lease liabilities:				
Operating leases	$ —	$ —	$ —	$ 110

At June 30, 2020, future minimum liabilities under ASC 842 for the Company's operating leases were as follows (in thousands):

Maturity of lease liabilities	As of June 30, 2020
2020 (remaining six months)	$ 68
2021	138
2022	105
2023	56
2024	10
2025 and thereafter	—
Total lease payments	377
Less: imputed interest	(47)
Present value of operating lease liabilities	$ 330

As of June 30, 2020, the weighted average remaining lease term for operating leases is 2.9 years, and the weighted average discount rate is 9.6%. The interest rate implicit in lease contracts is typically not readily determinable and as such, the Company uses an incremental borrowing rate based on a peer analysis using information available at the commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Licenses

MD Anderson - Total expenses related to the Company's license agreements with MD Anderson were $61,000 and $60,000 for the three months ended June 30, 2020 and 2019, respectively, and $122,000 and $120,000 for the six months ended June 30, 2020 and 2019, respectively.

HPI - On March 16, 2020, the Company entered into two agreements with a related party, Houston Pharmaceuticals, Inc. (HPI). The first agreement, which has a term of two years, continues a prior consulting arrangement with HPI on the Company's licensed molecules and requires payments for $43,500 per quarter to HPI. The second agreement, which can be cancelled with sixty days' notice by either party, allows the Company's employees access to laboratory equipment owned by HPI for a payment of $15,000 per quarter to HPI. Total expenses related to the Company's agreements with HPI were $58,500 and zero for the three months ended June 30, 2020 and 2019, respectively, and $266,000 and $75,000 for the six months ended June 30, 2020 and 2019, respectively.

Sponsored Research Agreements with MD Anderson - MBI entered into a Sponsored Laboratory Study Agreement with MD Anderson expiring in October 2021. The expenses recognized under this MD Anderson agreement with regards to the Sponsored Laboratory Study Agreement were $212,000 and $95,000 for the three months ended June 30, 2020 and 2019, respectively, and $358,000 and $189,000 for the six months ended June 30, 2020 and 2019, respectively.

8. Subsequent Events

In addition to the subsequent events discussed elsewhere in these notes, see below for a discussion of our subsequent events occurring after June 30, 2020.

2020 ATM Agreement - As previously reported, in July 2020, the Company entered into an At Market Issuance Sales Agreement (Agreement) with Oppenheimer & Co. Inc. (2020 ATM Agreement). Pursuant to the terms of the Agreement, the Company may sell from time to time through Oppenheimer shares of the Company’s common stock with an aggregate sales price of up to $15.0 million. As of the date of this report, there have been no issuances under the 2020 ATM Agreement.

2019 ATM Agreement - As previously reported, in July 2019, the Company entered into an At Market Issuance Sales Agreement (Agreement) with Oppenheimer & Co. Inc. (Oppenheimer) (2019 ATM Agreement). Pursuant to the terms of the Agreement, the Company may offer and sell, from time to time, Company common stock having an aggregate offering price of up to $15.0 million through Oppenheimer. In July 2020, the Company issued 1,301,126 shares of common stock at an average price of $1.47 per share through the 2019 ATM Agreement, resulting in net proceeds to the Company of $1.9 million. The Company paid a commission to Oppenheimer equal to 3.0% of the gross proceeds from the sale of its common stock under the 2019 ATM Agreement.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Form 10-Q, including the Management's Discussion and Analysis of Financial Condition and Results of Operations contains certain forward-looking statements. Historical results may not indicate future performance. Our forward-looking statements reflect our current views about future events, are based on assumptions and are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those contemplated by these statements.

Forward-looking statements include, but are not limited to, statements about:

- The impact the recent Coronavirus outbreak will have on our ability to continue our operations including our clinical trials and our ability to raise future financing;
- Our ability to continue our relationship with MD Anderson, including our ability to license future intellectual property resulting from our sponsored research agreements with MD Anderson;
- Our ability to obtain additional funding to commence or continue our clinical trials, fund operations and develop our product candidates;
- Our ability to satisfy any requirements imposed by the FDA (or its foreign equivalents) as a condition of our clinical trials proceeding or beginning as planned;
- The success, including the ability to recruit patients, of our clinical trials through all phases of clinical development;
- The need to obtain and retain regulatory approval of our drug candidates, both in the United States, in Poland, and in countries deemed necessary for future trials;
- Our ability to complete our clinical trials in a timely fashion and within our expected budget and resources;
- Compliance with obligations under intellectual property licenses with third parties;
- Any delays in regulatory review and approval of drug candidates in clinical development;
- Our ability to commercialize our drug candidates;
- Market acceptance of our drug candidates;
- Competition from existing therapies or new therapies that may emerge;
- Potential product liability claims;
- Our dependency on third-party manufacturers to successfully, and timely, supply or manufacture our drug candidates for our preclinical work and our clinical trials;
- Our ability to establish or maintain collaborations, licensing or other arrangements;
- The ability of our sublicense partners to successfully develop our product candidates in accordance with our sublicense agreements;
- The effects of future government shutdowns on our ability to raise financing;
- Our ability and third parties' abilities to protect intellectual property rights;
- Our ability to adequately support future growth; and
- Our ability to attract and retain key personnel to manage our business effectively.

We undertake no obligation to publicly update or revise any forward-looking statements, including any changes that might result from any facts, events, or circumstances after the date hereof that may bear upon forward-looking statements. Furthermore, we cannot guarantee future results, events, levels of activity, performance, or achievements.

Overview

Moleculin Biotech, Inc., a Delaware corporation, is a clinical stage pharmaceutical company focused on the treatment of highly resistant cancers and viruses. We have three core technologies, all of which are based on discoveries made at M.D. Anderson Cancer Center (MD Anderson). We have three drug candidates that are active in clinical trials. In 2019, those three drug candidates were active in five clinical trials in the US and Europe. Of these five clinical trials, two are primarily externally funded. For two of our internally funded trials, we successfully concluded the Phase 1 portion recently and are conducting follow-up observations. We anticipate pursuing pre-clinical work in 2020 for two additional Phase 1 trials expected to begin in 2021 sponsored by us and two to three other Phase 1 trials we expect to be externally sponsored.

We recently announced collaborations with outside entities to assist us in developing potential treatments for diseases like COVID-19. The preclinical work to evaluate the potential of molecules within the WP1122 portfolio of antimetabolites (which include inhibitors of glycolysis and glycosylation) against the viruses is mostly similar to the preclinical work we originally planned for 2020 to develop WP1122 for cancer indications. Accordingly, we believe the preclinical work under way

for WP1122 will support an IND application or its equivalent for either cancer-related or virus-related clinical trials (or both) in 2020. We consider the access to in vivo testing as the critical path of staying on this timeline.

Based on our positive pre-clinical and clinical activity thus far, we have narrowed our development focus to our nearest term opportunities, including Annamycin and the WP1122 portfolio, while relying on external funding, to the extent available, for other projects. In addition, the opportunity related to COVID-19 has pushed the development of the WP1122 portfolio to the forefront. Notwithstanding the emphasis on the WP1122 portfolio, we believe our overall narrowing of focus will allow us to limit our cash needs to the essential opportunities until we reach a significant value inflection point, although we will continue to require additional external capital during this period. In addition, institutional support for our technologies has increased and we believe such support may provide outside funding to help support future cash needs. Such expectations assume some form of government funding for WP1122 if it is successful in advancing from preclinical to clinical activity for the treatment of viruses in 2020, although we have no commitments at this time for such funding and can provide no assurances that such funding can be obtained.

Of our three clinical stage drug candidates, Annamycin is being studied for the treatment of relapsed acute myeloid leukemia (AML) and cancers metastasized to the lungs. WP1066, an Immune/Transcription Modulator (p-STAT3 inhibitor) is intended to target a wide range of tumors, including brain tumors such as glioblastoma (GBM) and pediatric brain tumors (like DIPG and medulloblastoma), as well as pancreatic cancer. We began and completed a "proof-of-concept" Phase 1 clinical trial in 2019 in Poland for a third drug, WP1220 (a molecule similar to WP1066), for the topical treatment of cutaneous T-cell lymphoma (CTCL). We intend to file a Phase 2 IND or its equivalent or to attempt to join efforts with a strategic partner in 2020 for the continued development of WP1220 as a topical therapy for CTCL. We are also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as antimetabolites, including Metabolism/Glycosylation Inhibitors.

We consider Annamycin to be a "next generation" anthracycline, unlike any currently approved anthracyclines, as it is designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity (two problems common to all currently approved anthracyclines). We recently received an independent expert cardiology assessment confirming the absence of cardiotoxicity in the first 14 patients treated with Annamycin in both our US and European Phase 1 clinical trials, validating Annamycin's lack of cardiotoxicity. Annamycin is currently in one Phase 1/2 clinical trial in Europe with the Phase 1 portion of another Phase 1/2 AML trial having been recently concluded in the US, subject to continued patient observations. The US trial met its primary endpoint of safety. As a result of discussions with the FDA, the Company will focus on establishing a recommended Phase 2 dose (RP2D) in its trial in Europe and generating additional safety and efficacy data as requested by the FDA.

In 2019, preclinical work on Annamycin demonstrated activity against certain cancers metastasized to the lungs. With this new data, we are planning to file in 2020 an IND or its equivalent for a clinical trial for the treatment of cancer metastasized to the lungs with Annamycin, although no assurances can be given that such trial will begin.

WP1066 is one of several Immune/Transcription Modulators designed to stimulate the immune response to tumors by inhibiting the errant activity of Regulatory TCells (TRegs) while also inhibiting key oncogenic transcription factors, including p-STAT3, c-Myc and HIF-1α. 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. WP1066 is currently in two US physician-sponsored Phase 1 clinical trials, one at MD Anderson for the treatment of glioblastoma ("GBM") in adults and another at Emory University for the treatment of pediatric brain tumors. The Emory trial has now treated three patients. Another physician-sponsored Phase 1 trial is being considered for the treatment of GBM with WP1066 in combination with radiation, although no assurances can be given that such trial will begin.

We are also developing new compounds within the WP1122 portfolio of antimetabolites, some of which are designed to exploit the potential uses of inhibitors of glycolysis such as 2-Deoxy-D-glucose (2-DG), which we believe may provide an opportunity to limit the energy available to tumors and virus host-cells by taking advantage of their high level of dependence on glucose in comparison to healthy cells. A key drawback to 2-DG is its lack of drug-like properties, including a short circulation time and poor tissue/organ distribution characteristics. Our lead Metabolism/Glycosylation Inhibitor, WP1122, is a prodrug of 2-DG that appears to improve the drug-like properties of 2-DG by increasing its plasma concentration and improving tissue/organ distribution. New research also points to the potential for 2-DG to be capable of enhancing the usefulness of checkpoint inhibitors and also its potential against viruses like the Coronavirus. Considering that 2-DG lacks sufficient drug-like properties to be practical in a clinical setting, we believe WP1122 has the potential to become an important drug, either as a single agent or to potentiate existing therapies, including checkpoint inhibitors and antiviral treatments. In March 2020, we entered into agreements with several outside research laboratories that are conducting research on molecules within the WP1122 portfolio

for antiviral properties against a range of viruses, including the Coronavirus. We have also added experts to our Science Advisory Board to support our anti-viral efforts.

The FDA has created a special emergency program for possible therapies, the Coronavirus Treatment Acceleration Program (CTAP). FDA comments that it uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful. As cited by the FDA on their CTAP website:

- "Immediately upon receipt, triaged requests from developers and scientists seeking to develop or evaluate new drug and biologic therapies …FDA will generally respond within a day.
- Provided ultra-rapid, interactive input on most development plans. Interactions have generally been prioritized based on a product's scientific merits, stage of development, and identification as a possible priority product in consensus USG documents.
- Provided ultra-rapid protocol review – within 24 hours of submission, in some cases.
- Completed review of single patient expanded access requests around-the-clock – and generally within 3 hours.
- Worked closely with applicants and other regulatory agencies to expedite quality assessments for products to treat COVID-19 patients and to transfer manufacturing to alternative or new sites to avoid supply disruption."

Comparing the intended turnaround times of the FDA above to its normal 60-day turnaround time for a pre-IND meeting request and 30 days for an IND review, these are expedited timelines. We plan on utilizing these aspects, which may shorten the various FDA review periods in connection with a potential IND for WP1122, although we can provide no assurance that the FDA will shorten its review period or eventually approve any IND application.

Although WP1122 is a prodrug of 2-DG, the WP1122 Portfolio includes other antimetabolites comprising prodrugs of alternate sugar structures that may also prove useful as antiviral and/or anticancer therapies. The Company is currently evaluating some of these other antimetabolite molecules for potential translational development.

Recent Business Developments

Below are recent business developments.

Annamycin

Update on Annamycin Clinical Development

On July 2, 2020, we announced an update to our clinical development plan for Annamycin. After consultation with both US and European regulatory agencies, we have mapped out a course for development of Annamycin for the treatment of relapsed AML. In our End of Phase 1 meeting with the FDA we agreed to expand our protocol-mandated testing for cardiotoxicity throughout the remainder of our European Phase 1 trial. The expansion of testing will provide additional safety data, including the continued development and evaluation of evidence supporting Annamycin's lack of cardiotoxicity, and efficacy data that both US and European regulators may consider as we prepare to transition to a Phase 2 clinical trial, which we believe will also be conducted in Europe.

Preclinical Data Confirms Efficacy of Annamycin in Lung Metastases

On June 25, 2020, we announced a presentation at the American Association of Cancer Research (AACR) Annual Meeting held from June 22nd-24th, 2020, illustrating a unique approach to creating drugs capable of reaching tumors hiding in organs where existing anticancer drugs cannot accumulate in therapeutic concentrations. A poster presentation entitled, "Targeting Cancer Sanctuary Sites: A Novel Approach to the Treatment of Lung Localized Tumors," provided an overview of data demonstrating that uniquely high uptake and retention of Annamycin in the lungs results in consistently high in vivo activity against wide range of lung-localized tumors in mice.

Submission to Expand Clinical Sites in European AML Trial

We announced on June 4, 2020, that we submitted requests to Polish regulatory authorities for approval to open two additional clinical sites for our Phase 1/2 clinical study of Annamycin for the treatment of AML. We subsequently received approval for the opening of these sites.

Approved to Accelerate European Clinical Trial

We announced on April 28, 2020, that we are now authorized by the Polish Department of Registration of Medicinal Products known as URPL to accelerate the Phase 1 dose escalation portion of our clinical trial of Annamycin for the treatment of AML. The URPL has allowed an amendment to the Annamycin clinical trial protocol, which among other things, includes an increase in the dose escalation increment between cohorts from 30 mg/m^2 to 60 mg/m^2. The clinical trial is currently recruiting for the 240 mg/m^2 cohort, so this amendment allows the next cohort to increase to 300 mg/m^2, assuming all requirements for safety are met with the 240 mg/m^2 cohort.

Positive Safety Data in EU AML Trial

On April 2, 2020, we announced that we completed the latest (210 mg/m^2) cohort in our European open label, single arm Phase 1/2 clinical trial of Annamycin for the treatment of relapsed AML. A total of 19 patients have been treated in the US and Europe, and all results continue to show Annamycin to be safe, and, especially, all have shown Annamycin to be free of cardiotoxicity. Of those patients, 10 have been treated at or above the FDA lifetime maximum anthracycline exposure.

WP1122

Independent Research Further Supports Glucose Metabolism as Important COVID-19 Target

On July 29, 2020, we announced that a recent publication by an independent research team at the University of Campinas in São Paulo, Brazil demonstrated that SARS-CoV-2 infection is supported by elevated glucose levels and that inhibition of glycolysis with 2-DG effectively eliminated viral load in vitro.

Independent In Vitro Testing Confirms Antiviral Activity of WP1122 in Coronavirus

On July 21, 2020, we announced that a second round of independent laboratory testing has confirmed the antiviral activity of WP1122 against coronavirus. We contracted with IIT Research Institute (an affiliate of the Illinois Institute of Technology, "IITR") for additional in vitro testing of our drug candidate, WP1122, in development as a possible treatment for COVID-19. The testing involved a cell viability assay in the VERO E6 cell line infected with SARS-CoV-2 and compared the therapeutic effects of 2-DG (the active ingredient in WP1122) alone with those of WP1122, a 2-DG prodrug. Importantly, the growth medium in this assay was carefully chosen to reflect the levels of glucose normally found in humans rather than the artificially high levels of glucose often used to accelerate in vitro testing.

Agreement to Produce WP1122 for Expanded Development

On July 15, 2020, we announced that we have entered into an agreement with Sterling Pharma USA LLC for US production of WP1122 to support our expanded development efforts in preparation for submitting a request to the FDA for IND status for WP1122 for the potential treatment of COVID-19.

Confirmatory In Vitro Analysis of WP1122 & Feedback from FDA on Pre-IND Meeting

On June 16, 2020, we announced that a repeat of previous in vitro testing has corroborated the antiviral potential of WP1122. Although developing in vitro data is an initial step and the data may not necessarily reflect the antiviral effects in vivo, the results of this repeated round of in vitro testing received on June 1, 2020, confirm that WP1122 has an antiviral effect on Human Coronavirus 229E ("HCoV-229E"), a surrogate of SARS-CoV-2, the virus responsible for COVID-19. As previously announced, on May 1, 2020, we submitted a Pre-IND meeting request with the FDA regarding the clinical development of WP1122 for the treatment of COVID-19. On June 2, 2020, we received the FDA's written response with guidance regarding application of the agency's requirements for clinical development programs in this circumstance. Based on guidance from the FDA, we will need additional studies to further assess WP1122's antiviral capability, and consistent with our previous guidance, we will continue to push forward with additional in vitro and in vivo testing with the goal of a possible IND filing by the end of 2020, in preparation for beginning a human clinical trial thereafter. The guidance provided thus far by us has been that we expect to file our request for IND status to test WP1122 for the treatment of COVID-19 patients during the second half of 2020. The opportunity to shorten that time frame may depend on our ability to use non-GLP (studies not done in strict adherence to "Good Laboratory Practices") toxicology data for the IND submission and exploring this possibility was a part of our request for feedback in our Pre-IND submission to the FDA. Based on the FDA's response, we now plan to present our non-GLP toxicology, when available, to the FDA in a second Pre-IND meeting request. While there can be no assurance that the FDA will allow our IND to go into effect on the basis of non-GLP toxicology data, we believe the possibility is worth pursuing, because it could significantly reduce our timeline to begin clinical trials for WP1122.

FDA grants Pre-IND Meeting Request

On May 27, 2020, we announced that the FDA has granted our request for a Pre-IND Meeting to provide guidance regarding our plan to study our drug candidate, WP1122, in a clinical trial for patients with COVID-19 (the disease caused by the SARS-CoV-2 coronavirus).

Head of NIAID Antiviral Drug Discovery and Development Center Joins COVID-19 Drug Development Team

On April 22, 2020, we announced that we have retained Dr. Richard Whitley to our Science Advisory Board to guide our development strategy for the WP1122 Portfolio for the potential treatment of COVID-19 and other viral diseases. Richard Whitley, M.D., is a Distinguished Professor of Pediatrics, Professor of Microbiology, Medicine and Neurosurgery; Loeb Eminent Scholar Chair in Pediatrics; Co-Director, Division of Pediatric Infectious Diseases; Vice-Chair, Department of Pediatrics; Senior Scientist, Department of Gene Therapy; Scientist, Cancer Research and Training Center; Faculty, Gene Therapy Center; Associate Director for Drug Discovery and Development and Senior Leader, Pediatric Oncology Program, O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham (UAB); and Co-Founder and Co-Director, Alabama Drug Discovery Alliance.

Dr. Whitley is responsible for the National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group whose role is to perform clinical trials of antiviral therapies directed against medically important viral diseases of children and adults including viruses considered as threats to human health. He participates in numerous Data Safety and Monitoring Boards for ongoing clinical studies. He is a past President of the Infectious Diseases Society of America and received the UAB President's Medal in 2007. In 2013, he was named as the inaugural recipient of the Distinguished Clinical Research Scholar and Educator in Residence at the NIH Clinical Center.

Agreement with ImQuest BioSciences to Expand Coronavirus Testing

We announced on April 20, 2020, that we entered into an agreement with ImQuest BioSciences to expand in vitro and in vivo testing of WP1122, our lead drug candidate for the treatment of COVID-19. ImQuest BioSciences is a preclinical CRO that provides expert services to evaluate the potential of new and novel pharmaceutical products for the treatment and prevention of viruses, bacteria, cancer and inflammatory diseases.

Leading Virologist Joins Development Team

On April 15, 2020, we announced that Dr. Dominique Schols of the Rega Institute has joined the Moleculin development team as a consultant and is now a member of our Science Advisory Board. The Rega Institute of Medical Research, Belgium, is one of the premier medical research institutes in Europe. Dr. Dominique Schols is Professor and Head of the Laboratory of Virology and Chemotherapy, Department of Microbiology and Immunology and Transplantation of the University of Leuven, Belgium.

Independent Research Finds Active Compound in WP1122 Reduces Coronavirus Replication in Vitro by 100%

On April 8, 2020, we announced that independent research found 2-DG to reduce replication of SARS-CoV-2, the virus that causes COVID-19, by 100% in in vitro testing. This cited research was a preprint, which is a preliminary report that has not undergone peer review. Moleculin's drug candidate, WP1122, is referred to as a "prodrug" of 2-DG whereby chemical elements are added to 2-DG to improve its delivery in vivo. Once administered, these added elements are removed by normal metabolic processes and what remains is 2-DG. As a result, 2-DG is the active compound in WP1122. In chemical terms, it is referred to as the active "moiety" (subpart) of WP1122.

Patent Filing to Cover New Coronavirus Drug Candidate

We announced on March 20, 2020, that a new patent application has been filed covering the use of WP1122 and its analogs as therapies to limit the ability of Coronavirus and other viruses to replicate. The patent application covers joint discoveries which came as a result of an ongoing sponsored research agreement.

WP1066

New Publication Combination of WP1066 and Radiation

On July 1, 2020, we announced that a peer-reviewed article published in Clinical Cancer Research reported findings that our STAT3 inhibitor, WP1066, used in combination with traditional whole brain radiation therapy (WBRT) resulted in long-term survivors and enhanced median survival time relative to monotherapy in mice with implanted human brain tumors.

Emory University Clinical Trial of WP1066 Begins Enrollment

On June 2, 2020, we announced that recruiting had begun and the first patient had been enrolled in the Emory University Phase 1 clinical trial of WP1066 for the treatment of brain tumors in children. The study is being conducted at the Aflac Cancer and Blood Disorders Center of Children's Healthcare of Atlanta.

SEC matters

On May 1, 2020, the Securities and Exchange Commission ("SEC") announced a temporary suspension of trading in our securities due to questions regarding the accuracy and adequacy of information in the marketplace about us and our securities, related to, among other things, statements made by us and others, in our Form 10-K filed March 19, 2020, in press releases on March 20, 2020 and April 8, 2020 and in other statements on March 19, 2020; March 20, 2020; and April 16, 2020 concerning the our business, including the status of development of WP1122 for potential application to COVID-19, and our ability to expedite regulatory approval of any such treatment. Pursuant to the suspension order, the trading halt was initiated at 9:30 a.m. EDT on May 4, 2020 and terminated at 11:59 p.m. EDT on May 15, 2020. Commencing May 18, 2020, the Nasdaq Stock Market placed a halt on the trading of our common stock pending the receipt of additional information, which we provided. This halt was lifted on May 28, 2020. We believe in the accuracy and adequacy of our public disclosures but can provide no assurances that we will not encounter future similar actions, which may adversely affect the holders of our common stock.

Results of Operations

The following table sets forth, for the periods indicated, data derived from our statement of operations (in thousands) and such changes in the periods are discussed below in approximate amounts:

Moleculin Biotech, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	3,329	2,099	6,535	5,031
General and administrative	1,653	1,484	3,463	3,075
Depreciation and amortization	52	49	98	97
Total operating expenses	5,034	3,632	10,096	8,203
Loss from operations	(5,034)	(3,632)	(10,096)	(8,203)
Other income (loss):				
Gain (loss) from change in fair value of warrant liability	(5,099)	2,407	(1,254)	2,936
Other income	17	—	22	—
Interest income, net	4	4	7	5
Net loss	$ (10,112)	$ (1,221)	$ (11,321)	$ (5,262)

Three Months Ended June 30, 2020 Compared to Three Months Ended June 30, 2019

Research and Development Expense. Research and development (R&D) expense was $3.3 million and $2.1 million for the three months ended June 30, 2020 and 2019, respectively. The increase of $1.2 million is mainly related to increased clinical trial activity, increased license fees and 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 Expense. General and administrative expense was $1.7 million and $1.5 million for the three months ended June 30, 2020 and 2019, respectively. The increase of $0.2 million was mainly attributable to increased stock-based compensation expense for annual employee stock options, and increased costs for directors and officer's liability insurance.

Gain (Loss) from Change in Fair Value of Warrant Liability. We recorded a net loss of $5.1 million in the second quarter of 2020 as compared to a net gain of $2.4 million in the second quarter of 2019, for the change in fair value on revaluation of our warrant liability associated with our warrants issued in conjunction with our stock offerings. We are required to revalue our liability-classified warrants at the time of each warrant exercise, if applicable, and at the end of each reporting period and reflect in the statement of operations a gain or loss from the change in fair value of the warrant in the period in which the change occurred. We calculated the fair value of the warrants outstanding using the Black-Scholes model. A gain results principally from a decline in our share price during the period and a loss results principally from an increase in our share price.

Six Months Ended June 30, 2020 Compared to Six Months Ended June 30, 2019

Research and Development Expense. R&D expense was $6.5 million and $5.0 million for the six months ended June 30, 2020 and 2019, respectively. The increase of $1.5 million is mainly related to increased clinical trial activity, increased license fees and 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 Expense. General and administrative expense was $3.5 million and $3.1 million for the six months ended June 30, 2020 and 2019, respectively. The increase of $0.4 million was mainly attributable to increased payroll costs for an additional finance employee, increased stock-based compensation expense for annual employee stock options, and increased costs for directors and officer's liability insurance.

Gain (Loss) from Change in Fair Value of Warrant Liability. We recorded a net loss of $1.3 million in the six months ended June 30, 2020 as compared to a net gain of $2.9 million in 2019, for the change in fair value on revaluation of our warrant liability associated with our warrants issued in conjunction with our stock offerings. We are required to revalue our liability-classified warrants at the time of each warrant exercise, if applicable, and at the end of each reporting period and reflect in the statement of operations a gain or loss from the change in fair value of the warrant in the period in which the change occurred. We calculated the fair value of the warrants outstanding using the Black-Scholes model. A gain results principally from a decline in our share price during the period and a loss results principally from an increase in our share price.

Liquidity and Capital Resources

The following table sets forth our primary sources and uses of cash for the period indicated (in thousands):

	Six Months Ended June 30,	
	2020	**2019**
Net cash used in operating activities	$ (9,275)	$ (9,194)
Net cash used in investing activities	(20)	(34)
Net cash provided by financing activities	15,303	20,802
Effect of exchange rate changes on cash and cash equivalents	(9)	(13)
Net increase in cash and cash equivalents	$ 5,999	$ 11,561

As of June 30, 2020, there was $0.3 million of cash on hand in Australia. We maintain a bank account in Australia and know of no related limitations impacting our liquidity in Australia.

Cash used in operating activities

Cash used in operations was $9.3 million for the six months ended June 30, 2020. This $0.1 million increase over the prior year period of $9.2 million was primarily due to: 1) payments for developing, manufacturing and testing drug product as we prepared for clinical trials; 2) an increase in R&D employee and contractor headcount and associated payroll costs; 3) an increase in paid sponsored research and related expenses; and 4) an increase in license fees. These are all a reflection of the ongoing clinical and pre-clinical activity and the associated increase in general and administrative support for our three core drug technologies.

Cash used in investing activities

Net cash used in investing activities was $20,000 for the six months ended June 30, 2020 compared to $34,000 for the six months ended June 30, 2019. The decrease relates to purchases in 2019 related to furniture and fixtures for our corporate apartment, as well as additional electronic equipment for employees and our corporate office.

Cash provided in financing activities

In July 2019, we entered into an At Market Issuance Sales Agreement (2019 ATM Agreement) with Oppenheimer & Co. Inc. (Oppenheimer). Pursuant to the terms of the 2019 ATM Agreement, we may offer and sell, from time to time, our common stock through Oppenheimer, acting as agent, through an "at the market offering" as defined in Rule 415(a)(4) (ATM Offering) promulgated under the Securities Act.

During the six months ended June 30, 2020, pursuant to the 2019 ATM Agreement, we issued 7,170,964 shares of common stock at an average price of $1.44 per share, resulting in net proceeds of $10.0 million. We paid a commission to Oppenheimer equal to 3.0% of the gross proceeds from the sale of our common stock under the 2019 ATM Agreement. Subsequent to the quarter ended June 30, 2020, we issued 1,301,126 shares of common stock at an average price of $1.47 per share resulting in net proceeds to the Company of $1.9 million in July 2020.

Subsequent to the quarter ended June 30, 2020, the Company entered into a new At Market Issuance Sales Agreement with Oppenheimer & Co. Inc. (2020 ATM Agreement) in July 2020. Pursuant to the terms of the 2020 ATM Agreement, the Company may sell from time to time through Oppenheimer shares of the Company's common stock with an aggregate sales price of up to $15.0 million. As of the date of this report, there have been no issuances under the 2020 ATM Agreement.

In February 2020, we entered into subscription agreements with institutional investors to purchase of 7,500,000 shares of our common stock and warrants to purchase 5,625,000 shares of common stock at a combined public offering price of $0.80 per share and related warrant resulting in gross proceeds of $6.0 million. Each warrant has an exercise price of $1.05 per share and will be exercisable six months from the date of issuance and will expire five years from the date they are first exercisable.

In April 2019, we completed subscription 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.

Additionally, during the second quarter of 2019, 1,413,018 shares were issued due to the exercise of various warrants related to past public offerings. Gross proceeds received due to these exercises approximated $1.6 million.

In March 2019, we completed an underwritten offering of 5,250,000 shares of our common stock and warrants to purchase 2,650,000 shares of common stock for gross proceeds of $5.3 million. Additionally, we sold 605,367 shares of our common stock to Lincoln Park Capital Fund, LLC for $0.9 million.

We believe that our existing cash and cash equivalents as of June 30, 2020 plus the cash raised subsequent to the quarter will be sufficient to fund our planned operations into the first quarter of 2021, without the issuance of additional equity for cash. Any such issuances should extend the funding of our planned operations beyond the first quarter of 2021. 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. Based on the Company's current assessment, the Company does not expect any material impact on its liquidity due to the worldwide spread of the COVID-19 virus.

We will not generate revenue from product sales unless and until we successfully complete development of, obtain regulatory approval for and begin to commercialize one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital to fund our future operations. Until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings and debt financings, and we may seek to raise additional capital through strategic collaborations. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations, which may cause dilution to our existing stockholders.

Critical Accounting Policies and Significant Judgments and Estimates

There have been no material changes to the Company's critical accounting policies and use of estimates from those disclosed in the Company's Form 10-K for the year ended December 31, 2019. For a discussion of our critical accounting policies and use of estimates, refer to Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Estimates in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2019.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

Not applicable to us, as we are a smaller reporting company.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

We maintain disclosure controls and procedures designed to ensure that material information required to be disclosed in our filings under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that material information is accumulated and communicated to our management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), as appropriate, to allow timely decisions regarding required disclosures. Our CEO and CFO have evaluated these disclosure controls and procedures as of the end of the period covered by this quarterly report on Form 10-Q and have determined that such disclosure controls and procedures were not effective due to the material weakness in our internal control over financial reporting discussed below.

In light of the material weakness described below, we performed additional procedures during the quarter and additional analysis and procedures post-closing to ensure our unaudited condensed consolidated financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, we believe that the condensed consolidated financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

A material weakness is a control deficiency (within the meaning of the Public Company Accounting Oversight Board Auditing Standard 1305) or combination of control deficiencies that result in more than a remote likelihood that a material misstatement of the annual or interim condensed consolidated financial statements will not be prevented or detected.

During the last quarter of fiscal 2016, and as our operational activities increased, management determined that it does not have sufficient segregation of duties within its accounting functions, which is a basic internal control. Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals. Management evaluated the impact of our failure to maintain effective segregation of duties on our assessment of our internal control over financial reporting and has concluded that the control deficiency represents a material weakness. A number of the issues related to segregation of duties were remediated with new information technology systems and policies and procedures during 2019. Management added additional accounting and IT personnel in 2019 and implemented a new accounting software system, accounting policies, and banking controls. Management intends to further enhance its accounting staff and enhance the controls surrounding its system of financial accounting and reporting, as soon as economically feasible and sustainable, to further remediate this material weakness. During 2020, we implemented an ERP system for electronic payments and further updated roles, policies and procedures within those systems.

We continuously seek to improve the efficiency and effectiveness of our internal controls. There have been no changes, except for items described above, in our internal control over financial reporting that occurred in the six months ended June 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Our employees are working remotely due to the COVID-19 pandemic, but we do not believe that our adjustments to how we work have materially impacted our internal controls over financial reporting. We continue to monitor and assess the potential impact of the COVID-19 pandemic, and the related shelter-in-place requirements, on our internal controls and strive to minimize the impact on our internal control design and operating effectiveness.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

For information regarding factors that could affect our results of operations, financial condition and liquidity, refer to the section entitled "Risk Factors" in Part I, Item 1A in our annual report on Form 10-K for the year ended December 31, 2019. Except as updated below, there have been no material changes from the risk factors previously disclosed in our annual report on Form 10-K for the year ended December 31, 2019 as filed with the SEC.

In May 2020, the SEC issued an order suspending the trading of our common stock and Nasdaq issued a trading halt in our common stock.

On May 1, 2020, the SEC announced a temporary suspension of trading in our securities due to questions regarding the accuracy and adequacy of information in the marketplace about us and our securities, related to, among other things, statements made by us and others, in our Form 10-K filed March 19, 2020, in press releases on March 20, 2020 and April 8, 2020 and in other statements on March 19, 2020; March 20, 2020; and April 16, 2020 concerning our business, including the status of WP1122 for potential application to COVID-19, and our ability to expedite regulatory approval of any such treatment. Pursuant to the suspension order, the trading halt was initiated at 9:30 a.m. EDT on May 4, 2020 and terminated at 11:59 p.m. EDT on May 15, 2020. Commencing May 18, 2020, the Nasdaq Stock Market placed a halt on the trading of our common stock pending the receipt of additional information. This halt was lifted on May 28, 2020. We believe in the accuracy and adequacy of our public disclosures but can provide no assurances that we will not encounter future similar actions, which may adversely affect the holders of our common stock.

The COVID-19 outbreak may affect the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to planned clinical trials and ultimately of reviews and approvals of our product candidates.

The COVID-19 outbreak may delay the approvals of our product candidates due to its effect on the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to planned clinical trials. The spread of COVID-19 may also slow potential enrollment of clinical trials and reduce the number of eligible patients for our clinical trials. The COVID-19 outbreak and mitigation measures also have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 outbreak impacts our business and operations will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact. We have relationships with contract research organizations to conduct certain pre-clinical programs and testing and other services in Europe and those business operations are subject to potential business interruptions arising from protective measures that may be taken by the governmental or other agencies or governing bodies. In addition, certain of our collaborative relationships with research facilities and academic research institutions in the United States, Europe and in Australia may be materially and adversely impacted by protective measures taken by those institutions or federal and state agencies and governing bodies to restrict access to, or suspend operations at, such facilities. Such protective measures, including quarantines, travel restrictions and business shutdowns, may also negatively affect our core operations.

If we breach any of the agreements under which we license patent rights or if we fail to meet certain development deadlines or exercise certain rights to technology, we could lose or fail to obtain license rights that are important to our business.

We license all of our technology from MD Anderson, and we must meet various payment and other obligations under our license agreements with MD Anderson. Our license agreements generally require that we meet various milestones by certain dates, each of which generally requires the payment of additional fees. To date, we have been able meet such milestones or have been able to enter into extensions with MD Anderson related to such milestones. However, our failure to meet any financial or other obligations under our license agreements in a timely manner could result in the loss of our rights to our core technologies.

We are a party to a number of license agreements with MD Anderson under which we are granted rights to intellectual property that are critical to our business and we expect that we will need to enter into additional license agreements in the future with MD Anderson based on development work we are pursuing under a sponsored research agreement. With respect to inventions arising from our sponsored research agreement, MD Anderson has provided us with an option to negotiate a royalty-bearing, exclusive license to any invention or discovery that is conceived or reduced to practice. However, regardless of such option to negotiate, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue a program based on that technology.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In April 2020, we issued a five-year warrant to purchase 100,000 shares of our common stock at exercise prices of $1.14 per share to a consultant. The consultant was an accredited investor. We believe that the issuance was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

Exhibit No.	Description
10.1+	Amendment No. 3 to Patent and Technology License Agreement between the Parties dated April 2, 2012, dated May 20, 2020, entered into between the Company and the Board of Regents of The University of Texas System, on behalf of The University of Texas M.D. Anderson Cancer Center
31.1*	Certification of Principal Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Accounting and Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.
+ Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MOLECULIN BIOTECH, INC.

Date: August 12, 2020

By: /s/ Walter V. Klemp

Walter V. Klemp,
Chief Executive Officer and Chairman
(Principal Executive Officer)

Date: August 12, 2020

By: /s/ Jonathan P. Foster

Jonathan P. Foster,
Executive Vice President & Chief Financial Officer
(Principal Financial and Accounting Officer)

AMENDMENT NO. 3 TO
PATENT AND TECHNOLOGY LICENSE AGREEMENT

This Amendment No. 3, effective this 20th day of May, 2020 ("Amendment No. 3 Effective Date"), to that certain Patent and Technology License Agreement between the Parties dated April 2, 2012, as previously amended by Amendment No.1 dated October 19, 2015 and Amendment No. 2 dated November 1, 2018 (as so amended, the "Original License"), is made by and between the Board of Regents ("Board") of The University of Texas System ("System"), an agency of the State of Texas, on behalf of The University of Texas M. D. Anderson Cancer Center (hereinafter "UTMDACC"), a member institution of System, and Moleculin Biotech, Inc. (hereinafter "Licensee"), a Delaware corporation having a principal place of business located at 5300 Memorial Dr., Suite 950, Houston, Texas 77007. Board, on behalf of UTMDACC, and Licensee may herein be referred to collectively as the "Parties."

RECITALS

A. Moleculin Biotech, Inc. is the assignee of the Original License pursuant to that certain Assignment and Assumption Agreement dated November 17, 2015. Accordingly, Moleculin Biotech, Inc. may be referenced herein as the "Licensee."

B. Board and Licensee desire to amend the Original License.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the sufficiency of which is hereby acknowledged, the Parties hereby agree to the following:

AMENDED TERMS

1. As consideration for this Amendment No. 3, Licensee shall pay UTMDACC, without invoice, the amount of $[***] not later than ten (10) days after the Amendment No. 3 Effective Date.

2. Subsections (b) and (c) of Section 13.2 of the Original License shall be deleted in their entirety and replaced with the following:

(b) within nine (9) months after the Amendment No. 3 Effective Date, file an INVESTIGATIONAL NEW DRUG APPLICATION with the FDA for a PHASE I STUDY for a LICENSED PRODUCT;

(c) within two and one-half (2.5) years after the Amendment No. 3 Effective Date, commence a PHASE I STUDY for a LICENSED PRODUCT; and

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. THE REDACTED TERMS HAVE BEEN MARKED WITH THREE ASTERISKS [***]

(d) within four and one-half (4.5) years after the Amendment No. 3 Effective Date, commence a PHASE II STUDY for a LICENSED PRODUCT.

As used in Subsections 13.2(c) and 13.2(d) above, a PHASE I STUDY, or a PHASE II STUDY, shall be deemed to commence upon the administration of a LICENSED PRODUCT or placebo to the first patient enrolled in the PHASE I STUDY, or PHASE II STUDY, respectively.

Licensee may extend any of the deadlines for achieving the milestones set forth in Subsections (b) – (d) above, up to a maximum of three (3) times, upon written notice to UTMDACC requesting an extension and full payment of the Extension Fee, as defined below, prior to expiration of the respective deadline. For purposes of this Agreement, the term "Extension Fee" shall mean the amount set forth in Table 13.2 below for each deadline extension request. Upon payment of each Extension Fee with respect to any of such milestones, an additional six months will be added to the time for completion of such milestone and all other as yet unmet milestones in Subsections (b) – (d) above. It is understood and agreed that time is of the essence with respect to payment of the Extension Fee, and failure to timely pay an Extension Fee shall not be subject to any cure period. In no event shall any of the deadlines in Subsections (b) – (d) above be subject to more than three (3) six month extensions.

Table 13.2

Extension	Extension Fee
First six (6) month extension	$[***]
Second six (6) month extension	$[***]
Third six (6) month extension	$[***]

3. Licensee shall be solely responsible for timely submission of this Amendment No. 3, or any portions thereof, to any securities exchange or any governmental or quasi- governmental entity if required by applicable law or regulation.

4. This Amendment No. 3 shall be construed and enforced in accordance with the laws of the United States of America and the State of Texas, without regard to its conflict of law provisions.

5. The Parties acknowledge and agree that, except as set forth in this Amendment No. 3, the terms and conditions of the Original License shall remain in full force and effect. Moreover, this Amendment No. 3 shall not modify or supersede any other agreements between the Parties.

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. THE REDACTED TERMS HAVE BEEN MARKED WITH THREE ASTERISKS [***]

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Amendment No. 3.

BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, on behalf of THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER

By [***]
Printed Name: [***]
Title: [***]
Date: May 20, 2020

MOLECULIN BIOTECH, INC.

By /s/ Walter V. Klemp
Printed Name: Walter V. Klemp
Title: Chairman & CEO
Date: May 20, 2020

Approved as to Content:

By [***]
[***], J.D., Ph.D.
Senior Vice President
Res. Administration & Industry Relations Strategic Industry Ventures
M. D. Anderson Cancer Center

Date: May 20, 2020

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. THE REDACTED TERMS HAVE BEEN MARKED WITH THREE ASTERISKS [***]

Exhibit 31.1

OFFICER'S CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Walter V. Klemp, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Moleculin Biotech, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 12, 2020

By: /s/ Walter V. Klemp
Walter V. Klemp
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

OFFICER'S CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jonathan P. Foster, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Moleculin Biotech, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 12, 2020

By: /s/ Jonathan P. Foster
Jonathan P. Foster
Executive Vice President and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Walter Klemp, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C 78m or 78o(d)); and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2020

By: /s/ Walter V. Klemp
Walter V. Klemp
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Moleculin Biotech, Inc. and will be retained by Moleculin Biotech, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-Q for the quarter ended June 30, 2020 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan Foster, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C 78m or 78o(d)); and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2020

By: /s/ Jonathan P. Foster
Jonathan P. Foster
Executive Vice President and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to Moleculin Biotech, Inc. and will be retained by Moleculin Biotech, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.