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 March 31, 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 ☐	Smaller reporting company ☒
Non-accelerated filer ☐	Emerging growth company ☒
Accelerated filer ☐	

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 60,403,164 shares of common stock outstanding at May 6, 2020.

Moleculin Biotech, Inc.

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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)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 11,649	$ 10,735
Prepaid expenses and other current assets	2,138	2,749
Total current assets	13,787	13,484
Furniture and equipment, net	271	316
Intangible assets	11,148	11,148
Operating lease right-of-use asset	266	287
Total assets	$ 25,472	$ 25,235
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,206	$ 2,153
Accrued expenses and other current liabilities	2,029	1,417
Total current liabilities	3,235	3,570
Operating lease liability - long-term, net of current portion	248	276
Warrant liability - long-term	6,697	5,818
Total liabilities	10,180	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 March 31, 2020 and December 31, 2019, 53,227,700 and 45,727,700 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	53	46
Additional paid-in capital	56,011	55,055
Accumulated other comprehensive income (loss)	(2)	31
Accumulated deficit	(40,770)	(39,561)
Total stockholders' equity	15,292	15,571
Total liabilities and stockholders' equity	$ 25,472	$ 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 March 31,	
	2020	**2019**
Revenues	$ —	$ —
Operating expenses:		
Research and development	3,206	2,932
General and administrative	1,810	1,591
Depreciation and amortization	46	48
Total operating expenses	5,062	4,571
Loss from operations	(5,062)	(4,571)
Other income:		
Gain from change in fair value of warrant liability	3,845	529
Other income, net	5	—
Interest income, net	3	1
Net loss	$ (1,209)	$ (4,041)
Net loss per common share - basic and diluted	$ (0.02)	$ (0.14)
Weighted average common shares outstanding, basic and diluted	49,930,997	29,064,913
Net Loss	$ (1,209)	$ (4,041)
Other comprehensive income (loss):		
Foreign currency translation	(33)	(11)
Comprehensive loss	$ (1,242)	$ (4,052)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (1,209)	$ (4,041)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	46	48
Stock-based compensation	397	348
Gain from change in fair value of warrant liability	(3,845)	(529)
Operating lease, net of sublease receipts	99	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	611	9
Accounts payable	(947)	1,553
Accrued expenses and other current liabilities	506	(1,235)
Net cash used in operating activities	(4,342)	(3,847)
Cash flows from investing activities:		
Purchase of fixed assets	(2)	(15)
Net cash used in investing activities	(2)	(15)
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	5
Proceeds from sale of common stock, net of issuance costs	5,291	5,516
Net cash provided by financing activities	5,291	5,521
Effect of exchange rate changes on cash and cash equivalents	(33)	$ (11)
Net change in cash and cash equivalents	914	1,648
Cash and cash equivalents, at beginning of period	10,735	7,134
Cash and cash equivalents, at end of period	$ 11,649	$ 8,782
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ —	$ 1
Cash paid for taxes	$ 6	$ 2
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued liabilities	$ 23	$ 41

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31, 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

	Three Months Ended March 31, 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

See accompanying notes to 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 via the development of its oncology 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 in June 2018, to begin preclinical development in Australia for WP1732, an analog of WP1066. 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 with six drug candidates, 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 Metabolism/Glycosylation Inhibitor portfolio, WP1122. The Company's clinical stage drugs are Annamycin, an anthracycline which is in two Phase 1/2 studies for the treatment of relapsed or refractory acute myeloid leukemia, (AML), WP1066, an Immune/Transcription Modulator, which is in a Phase 1 clinical trial in the United States of America (US) for the treatment in glioblastoma, 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. A fifth Phase 1 trial for the treatment of pediatric brain tumors at Emory University has been approved by the US Food and Drug Administration (FDA) and began recruiting patients in 2020.

The Company believes Annamycin is 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 of all currently approved anthracyclines. Annamycin is currently in two Phase 1/2 clinical trials, and preliminary clinical data suggests that it may have the potential to become the first therapy suitable for the majority of relapsed or refractory AML patients regardless of gene mutations. During 2019, these trials have so far demonstrated the safety, including no cardiotoxicity, and has begun to show some initial efficacy. 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.

WP1066 is one of several Immune/Transcription Modulators 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 preparations to file a Phase 2 IND or its equivalent have begun.

The Company is also developing new prodrugs to exploit the potential uses of 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 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. In March 2020, we entered into an agreement with an outside research center who will conduct research on WP1122 for antiviral properties against a range of viruses, including Coronavirus. Additional research with other contractors has started.

Drug Candidates - Within the Company's core technologies, it currently has six drug candidates representing three substantially different approaches to treating cancer. 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 trials open in the US and Poland. The US Phase 1 portion of the Phase 1/2 trial reached key safety end points in early 2020 and the Company plans to discuss next steps with the FDA. The Phase 1/2 trial in Poland continues its dose escalation and is in its fifth cohort. So far both trials have proven 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:

- WP1066 has an approved physician-sponsored clinical trial open for enrollment and dosing patients for the treatment of brain tumors and a second physician-sponsored Phase 1 trial for the potential treatment of pediatric brain tumors has begun recruitment.

- 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, which the Company expects to prepare for in the near future.

- WP1066 along with another analog, WP1732, are being evaluated for the potential treatment of AML, 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.

- WP1122 and WP1234 are being evaluated for their potential to treat brain tumors and pancreatic cancer via their ability to inhibit glycolysis. The Company has begun preclinical work supporting WP1122 as a treatment for cancers and some viruses, including the Coronavirus which the Company believes may support an IND or its equivalent.

Clinical Trials - The Company has concluded the initial Phase 1 portion of its Phase 1/2 trial 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 clinical trial in Poland 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 trial is in its fifth cohort in the dose ranging Phase 1 portion of the trial. In September 2018, the physician sponsored WP1066 Phase I 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 Phase 1 trial for another physician-sponsored clinical trial for the potential treatment of pediatric brain tumors began recruitment of patients. 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, which the Company expects to prepare for in the near future.

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. 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 our 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 March 31, 2020, the Company has incurred an accumulated deficit of $40.8 million since inception and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of March 31, 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 SEC pursuant to Section 12(k) of the Securities Exchange Act of 1934, as amended, ordered the temporary suspension of trading in the securities of the Company because of questions regarding the accuracy and adequacy of information in the marketplace about the Company and its securities. Pursuant to the suspension order, the suspension

commenced on May 4, 2020 and terminates on May 15, 2020. As of the date of this report, the Company has submitted a petition to terminate the suspension, but there is no assurance that the Company will be successful. The Company believes it will be able to demonstrate the accuracy and adequacy of its public disclosures, but the SEC may determine to extend the trading suspension until such time that it believes the information in the marketplace about the Company and its securities is accurate and adequate.

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):

	March 31, 2020	December 31, 2019
Vendor prepayments and deposits	$ 1,372	$ 1,857
Prepaid insurance	150	352
Non-trade receivables	1	1
Related party receivables	—	10
Other current assets	615	529
Total prepaid expenses and other current assets	$ 2,138	$ 2,749

Vendor prepayments at March 31, 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 $0.3 million at March 31, 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 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, account payables, accrued expenses and its warrant liability. The carrying amount of non-trade receivables, accounts payables, 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 March 31, 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 March 31, 2020:	$ 6,697	$ —	$ —	$ 6,697
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 first quarter and then is adjusted for the issuances and exercises that occurred during the first 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 March 31, 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
Change in fair value - net	—	(3,845)	(3,845)
Balance, March 31, 2020	$ —	$ 6,697	$ 6,697

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 March 31, 2020 and 2019, approximately 18.4 million and approximately 6.7 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. 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, 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):

	March 31, 2020	December 31, 2019
Accrued payroll and bonuses	$ 623	$ 436
Accrued legal and professional fees	302	272
Accrued clinical testing	262	93
Related party payable	225	99
Accrued drug manufacturing costs	219	49
Accrued license fees and sponsored research agreements	212	201
Operating lease liability - current	107	103
Accrued other	79	164
Total accrued expenses and other current liabilities	$ 2,029	$ 1,417

4. Warrants

At March 31, 2020, and December 31, 2019, respectively, the Company has the following warrants outstanding,

	Number of Shares Under Outstanding Warrants at March 31, 2020	Number of Shares Under Outstanding Warrants at December 31, 2019	Weighted Average Exercise Price at March 31, 2020	Remaining Contractual Life at March 31, 2020 (No. Years)
Liability Classified Warrants [1]				
Issued February 2017	404,002	404,002	$ 1.50	1.9
Issued February 2018	2,273,700	2,273,700	$ 2.80	3.4
Issued June 2018 [2]	742,991	742,991	$ 2.03	3.7
Issued March 2019	1,585,500	1,585,500	$ 1.10	4.0
Issued April 2019	5,250,000	5,250,000	$ 1.75	4.1
Issued February 2020	6,150,000	—	$ 1.05	5.3
	16,406,193	10,256,193	$ 1.58	
Equity Classified Warrants				
Issued May 2016 - Bonwick	107,802	107,802	$ 7.50	1.1
Issued July 2017 - Consulting [3]	150,000	150,000	$ 2.61	2.3
Issued April 2018 - Consulting	100,000	100,000	$ 3.00	1.0
Issued August 2019 - Consulting	150,000	150,000	$ 1.64	2.4
	507,802	507,802	$ 3.44	
Balance outstanding	16,913,995	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 purchase32,779 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 our stock price.

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

	March 31, 2020			December 31, 2019		
Risk-free interest rate	0.2 %	to	1.5 %	1.6 %	to	1.7 %
Volatility	111.4 %	to	120.6 %	97.5 %	to	107.5 %
Expected life (years)	1.9	to	5.5	2.1	to	4.3
Dividend yield	—%			—%		

A summary of the Company's liability classified warrant activity during the three months ended March 31, 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	5.3
Exercised	—	$ —	$ —	$ —	—
Expired	—	$ —	$ —	$ —	—
Balance at March 31, 2020	16,406,193	$ 1.05	$ 2.80	$ 1.58	4.4
Vested and Exercisable at March 31, 2020	10,256,193	$ 1.10	$ 2.80	$ 1.89	3.8

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 three months ended March 31, 2020, see Note 2. Basis of presentation, principles of consolidation and significant accounting policies - Fair Value of Financial Instruments.

Equity Classified Warrants

The Company recorded stock compensation expense for the non-employee consulting agreement of zero and $2,000 for the three months ended March 31, 2020 and 2019, respectively. At March 31, 2020, there was no unrecognized stock compensation expense related to the Company's equity-classified warrants.

5. Equity

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 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. 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 three months ended March 31, 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 6, 2018, 4.5 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 March 31, 2020, there were 297,093 shares remaining to be issued under the 2015 Stock Plan.

Stock-based compensation for the three months ended March 31, 2020 and 2019, are as follows (in thousands):

	Three Months Ended March 31,	
	2020	**2019**
General and administrative	$ 334	$ 302
Research and development	63	46
Total	$ 397	$ 348

The Company did not grant any stock-based awards during the three months ending March 31, 2020.

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 months ended March 31, 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 March 31, 2020, the Company maintained a full valuation allowance for all deferred tax assets.

The Company recorded no income tax provision for the three months ended March 31, 2020 and 2019, respectively. The effective tax rate for the three months ended March 31, 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 our condensed consolidated financial statements for the three months ended March 31, 2020. We continue 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 our commitments and contingencies as of March 31, 2020.

Lease Obligations Payable

During the three months ended March 31, 2020, the Company did not enter into any lease arrangements requiring any additional right-of-use assets or liabilities to be recorded.

During the three months ended March 31, 2020, the Company recognized $29,000 of lease costs, $4,000 of expenses related to short-term leases and $7,000 of lease costs for variable lease payments. During the three months ended March 31, 2019, the Company recognized $8,000 of lease costs, $14,000 of expenses related to short-term leases and $5,000 of lease costs for variable lease payments. The Company recorded approximately $10,000 in sublease income from a related party for the three months ended March 31, 2020. Sublease income is recorded as other income, net on the Company's condensed consolidated statement of operations and comprehensive loss.

At March 31, 2020, the cash paid for the Company's operating leases and right-of-use assets was as follows (in thousands):

	Three Months Ended March 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 33	$ 8
Right-of-use assets obtained in exchange for lease liabilities:		
Operating leases	$ —	$ 110

At March 31, 2020, future minimum liabilities under ASC 842 for the Company's operating leases were as follows (in thousands):

Maturity of lease liabilities	**As of March 31, 2020**
2020 (remaining nine months)	$ 101
2021	138
2022	105
2023	56
2024	10
2025 and thereafter	—
Total lease payments	410
Less: imputed interest	(55)
Present value of operating lease liabilities	$ 355

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 March 31, 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 $207,500 and $75,000 for the three months ended March 31, 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 $179,000 and $95,000 for the three months ended March 31, 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 March 31, 2020.

ATM Issuances Under the Oppenheimer Agreement - As previously reported, in July 2019, the Company entered into an At Market Issuance Sales Agreement (Agreement) with Oppenheimer & Co. Inc. (Oppenheimer). Pursuant to the terms of the Agreement, the Company may offer and sell, from time to time, Company 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. On July 24, 2019, pursuant to the ATM Offering, the Company filed a prospectus supplement pursuant to which 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 (ATM Prospectus Supplement). From April 8, 2020 to April 16, 2020, the Company issued 7,170,964 shares of common stock at an average price of $1.44 per share through the ATM Prospectus Supplement, resulting in net proceeds to the Company of $10.0 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 ATM Prospectus Supplement. After the completion of the foregoing issuances, the Company will have 60,403,164 shares of common stock outstanding.

Warrant Exercises - Subsequent to March 31, 2020 and through the date of filing of these financial statements4,500 shares were issued due to the exercise of various liability warrants related to past public offerings. Gross proceeds received due to these exercises approximated $5,000.

Equity Warrants and Stock Options - Subsequent to March 31, 2020 and through the date of filing of these financial statements,100,000 equity warrants were issued to a consultant with an exercise price of $1.08, with vesting contingent on certain conditions. In addition,25,000 options were issued to a consultant with an exercise price of $1.26, a 5 year term and vesting over a one-year period in four equal quarterly installments under the 2015 Stock Plan. Lastly,20,000 options were issued to a science advisory board member with a term of 10 years vesting in four equal quarterly installments and an exercise price of $1.47.

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 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 four clinical trials in the US and Europe with a fifth that began recruiting patients in April 2020. 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 preparing to potentially move into Phase 2 trials. We anticipate laying the groundwork in 2020 for two additional Phase 1 trials expected to begin in 2021 sponsored by us and two other Phase 1 trials we expect to be externally sponsored.

We recently announced a collaboration with a major Texas university institution to evaluate our drug candidate, WP1122, and now this has been followed by collaborations with additional entities who bring additional expertise in developing potential treatments for diseases like COVID-19. The preclinical work to evaluate WP1122's potential against the Coronavirus is similar to preclinical work originally planned for 2020 to develop against cancer indications, supporting a cancer-related Investigational New Drug (IND) application for clinical trials in 2021.

Based on our positive clinical activity thus far, we have narrowed our development focus to our nearest term opportunities, including Annamycin, WP1222 and WP1220, while relying on external funding for other projects. In addition, the opportunity related to COVID-19 has pushed the development of WP1122 to the forefront. Notwithstanding the emphasis on WP1122, we believe our overall narrowing of focus will allow us to reduce our cash needs 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 reduce future cash needs. Such expectations assume some form of government funding for WP1122 if it is successful in bridging from preclinical to clinical activity 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 or refractory 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 and 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) and we are planning to expand development of this drug into a Moleculin Phase 2 trial. We are also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as 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 recently concluding in the US. Upon receipt of further data from the European Phase 1 trial, we plan to seek agreement with the FDA for accelerated approval of Annamycin based on a pivotal Phase 2 AML trial sponsored by us, although there is no assurance that the FDA will agree with our proposal.

In 2019, preclinical work on Annamycin demonstrated activity against certain cancers metastasized to the lungs. With this new data, we are planning to start a Moleculin-sponsored US Phase 1 trial at MD Anderson 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 a US physician-sponsored Phase 1 trial for the treatment of glioblastoma ("GBM") and another institutionally sponsored Phase 1 trial has begun recruiting for the treatment of pediatric brain tumors. 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 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 circulation time 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 will conduct research on WP1122 for antiviral properties against a range of viruses, including 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.

Recent Business Developments

Below are recent business developments.

Annamycin

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/m2 to 60 mg/m2. The clinical trial is currently recruiting for the 240 mg/m2 cohort, so this amendment allows the next cohort to increase to 300 mg/m2, assuming all requirements for safety are met with the 240 mg/m2 cohort.

Positive Safety Data in EU AML Trial

On April 2, 2020, we announced that we completed the latest (210 mg/m2) cohort in our European open label, single arm Phase 1/2 clinical trial of Annamycin for the treatment of relapsed or refractory 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, 10 have been treated at or above the FDA lifetime maximum anthracycline exposure.

WP1122

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 WP1122 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. 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 is 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.

SEC matters

On May 1, 2020, the SEC pursuant to Section 12(k) of the Securities Exchange Act of 1934, as amended, ordered the temporary suspension of trading in the securities of Moleculin because of questions regarding the accuracy and adequacy of information in the marketplace about Moleculin and its securities. Pursuant to the suspension order, the suspension commenced at 9:30 a.m. EDT on May 4, 2020 and terminates at 11:59 p.m. EDT on May 15, 2020. As of the date of this report, we have submitted a petition to terminate the suspension, but there is no assurance that we will be successful. We believe we will be able to demonstrate the accuracy and adequacy of our public disclosures, but the SEC may determine to extend the trading suspension until such time that it believes the information in the marketplace about us and our securities is accurate and adequate.

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 March 31,	
	2020	**2019**
Revenues	$ —	$ —
Operating expenses:		
Research and development	3,206	2,932
General and administrative	1,810	1,591
Depreciation and amortization	46	48
Total operating expenses	5,062	4,571
Loss from operations	(5,062)	(4,571)
Other income (expense):		
Gain from change in fair value of warrant liability	3,845	529
Other income	5	—
Interest income, net	3	1
Net loss	$ (1,209)	$ (4,041)

Three Months Ended March 31, 2020 Compared to Three Months Ended March 31, 2019

Research and Development Expense. Research and development (R&D) expense was $3.2 million and $2.9 million for the three months ended March 31, 2020 and 2019, respectively. The increase of $0.3 million is mainly related to increased clinical trial activity, increased license fees and sponsored research agreements, costs related to manufacturing of additional drug product and two additional employees in research and development headcount.

General and Administrative Expense. General and administrative expense was $1.8 million and $1.6 million for the three months ended March 31, 2020 and 2019, respectively. The increase of $0.2 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 from Change in Fair Value of Warrant Liability. We recorded a net gain of $3.8 million in the first quarter of 2020 as compared to a net gain of $0.5 million in the first 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.

Liquidity and Capital Resources

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

	Three Months Ended March 31,	
	2020	2019
Net cash used in operating activities	$ (4,342)	$ (3,847)
Net cash used in investing activities	(2)	(15)
Net cash provided by financing activities	5,291	5,521
Effect of exchange rate changes on cash and cash equivalents	(33)	(11)
Net increase in cash and cash equivalents	$ 914	$ 1,648

As of March 31, 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 there.

Cash used in operating activities

Cash used in operations was $4.3 million for the three months ended March 31, 2020. This $0.5 million increase over the prior year period of $3.8 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 $2,000 for the three months ended March 31, 2020 compared to $15,000 for the three months ended March 31, 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 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.

During the three months ended 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 net proceeds of $4.7 million after deducting the underwriting discount and estimated offering expenses and 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 March 31, 2020 combined with the shares we sold in April 2020 through the At Market Issuance Sales Agreement 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 long-term development timeline and 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

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following accounting policies are the most critical to aid in fully understanding and evaluating our reported financial results, and they require our most difficult, subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain**.**

Research and Development Costs

We record accrued expenses for estimated costs of our research and development activities conducted by third-party service providers, which include the conduct of pre-clinical and clinical studies and preparation for clinical trials and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and we include these costs in accrued liabilities in the balance sheets and within research and development expense in the statements of operations. These costs are a significant component of our research and development expenses. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these third parties.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. To date, there have been no material differences from our accrued expenses to actual expenses.

Impairment of Long-Lived Assets

Management evaluates the recoverability of its property and equipment and amortizable intangible assets for possible impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable or at a minimum annually during the fourth quarter of the year. Recoverability of these assets is measured by a comparison of the carrying amounts to the future undiscounted cash flows the assets are expected to generate. If such review indicates that the carrying amount of property and equipment and amortizable intangible assets is not recoverable, the carrying amount of such asset is reduced to fair value.

Acquired in-process research and development (IPR&D) assets are considered indefinite lived until the completion or abandonment of the associated research and development efforts. Management evaluates the recoverability of its IPR&D assets for possible impairment annually during the fourth quarter or whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of IPR&D assets is measured by a comparison of the carrying amounts to its fair value. If such review indicates that the carrying amount of IPR&D assets is not recoverable, the carrying amount of such asset is reduced to fair value.

Accounting for warrants

We have issued warrants to purchase shares of common stock related to equity transactions in 2017, 2018, 2019 and 2020. We account for our warrants issued in accordance with Accounting Standards Codification (ASC) Topic 480, Distinguishing Liabilities from Equity, ASC Topic 505, Equity, ASC Topic 815, Derivatives and Hedging, and ASC Topic 718, Compensation—Stock Compensation. Warrants are classified as liabilities when the Company may be required to settle a

warrant exercise in cash and classified as equity when the Company settles a warrant exercise in shares of its common stock. Based on this guidance, we determined that certain of our warrants to purchase shares of common stock related to equity transactions meet the criteria for classification as a liability. Accordingly, the warrants were classified as a warrant liability and are subject to fair value remeasurement at exercise and balance sheet date with the changes in fair value recognized in earnings.

Our financial instruments consist primarily of non-trade receivables, account payables, accrued expenses, and a warrant liability. The carrying amount of non-trade receivables, accounts payables, and accrued expenses approximates their fair value because of the short-term maturity of such.

We have categorized our assets and liabilities that are valued at fair value on a recurring basis into three-level fair value hierarchy in accordance with 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.

Our financial assets and liabilities recorded at fair value on a recurring basis include the fair value of our warrant liability discussed above. The fair value of our liability classified warrants associated with the February 2017, February 2018, June 2018, March 2019, April 2019 and February 2020 Offerings (Offerings) are included in long-term liabilities on the accompanying financial statements as of March 31, 2020 and December 31, 2019.

We estimated the fair value of the warrant liability of a liability classified warrants pursuant to ASC Topic 820 as of their issuance date for financial reporting purposes, when exercised and balance sheet date. We used the Black-Scholes option pricing model (BSM) to determine the fair value of the warrants which is an acceptable method in accordance with GAAP. The BSM requires the use of a number of assumptions including volatility of the stock price, the weighted average risk-free interest rate, and the weighted average term of the Warrant.

The risk-free interest rate assumption is based upon observed interest rates on zero coupon US Treasury bonds whose maturity period is appropriate for the term of the warrants and is calculated by using the average daily historical stock prices through the day preceding the grant date.

Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the expected life of the warrants. Beginning in 2020, we use the volatility of our stock in the BSM as we now have sufficient historic data in our stock price. Prior to 2020, we used the historical volatility of peer entities combined with our own due to the lack of sufficient historical data of our stock price

Changes in the fair value of our liability classified warrants during the reporting period are reflected as a gain (loss) from change in fair value of warrant liability in other income (expense) in our condensed consolidated statement of operations and comprehensive loss.

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 as disclosed 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 the 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 has been no changes, except for items described above, in our internal control over financial reporting that occurred in the three months ended March 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Specifically, 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 access 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.

The SEC issued an order suspending the trading of our common stock.

On May 1, 2020, the SEC pursuant to Section 12(k) of the Securities Exchange Act of 1934, as amended, ordered the temporary suspension of trading in the securities of Moleculin because of questions regarding the accuracy and adequacy of information in the marketplace about Moleculin and its securities. Pursuant to the suspension order, the suspension commenced at 9:30 a.m. EDT on May 4, 2020 and terminates at 11:59 p.m. EDT on May 15, 2020. As of the date of this report, we have submitted a petition to terminate the suspension, but there is no assurance that we will be successful. We believe we will be able to demonstrate the accuracy and adequacy of our public disclosures, but the SEC may determine to extend the trading suspension until such time that it believes the information in the marketplace about us and our securities is accurate and adequate.

With respect to the COVID-19 outbreak specifically, such outbreak could also potentially 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 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 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.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION.

On May 1, 2020, the SEC pursuant to Section 12(k) of the Securities Exchange Act of 1934, as amended, ordered the temporary suspension of trading in the securities of Moleculin because of questions regarding the accuracy and adequacy of information in the marketplace about Moleculin and its securities. Pursuant to the suspension order, the suspension commenced at 9:30 a.m. EDT on May 4, 2020 and terminates at 11:59 p.m. EDT on May 15, 2020. As of the date of this report, we have submitted a petition to terminate the suspension, but there is no assurance that we will be successful. We believe we will be able to demonstrate the accuracy and adequacy of our public disclosures, but the SEC may determine to extend the trading suspension until such time that it believes the information in the marketplace about us and our securities is accurate and adequate.

ITEM 6. EXHIBITS

Exhibit No.	Description
4.1	Form of Warrant Agreement issued in February 2020 offering (incorporated by reference to Exhibit 4.1 of the Form 8-K filed February 6, 2020)
4.2	Form of Placement Agent Warrant Agreement issued in February 2020 offering (incorporated by reference to Exhibit 4.2 of the Form 8-K filed February 6, 2020)
10.1	Material Transfer Agreement between the Company and The University of Texas Medical Branch at Galveston, d/b/a UTMB Health ("UTMB"), a health institution of The University of Texas System dated February 23, 2020 (incorporated by reference to Exhibit 1.1 of the Form 8-K filed March 17, 2020)
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.

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: May 11, 2020

By: /s/ Walter V. Klemp

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

Date: May 11, 2020

By: /s/ Jonathan P. Foster

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

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.

May 11, 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.

May 11, 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 March 31, 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: May 11, 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 March 31, 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: May 11, 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.