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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, 2021
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
(Address of principal executive offices)

77007
(Zip Code)

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

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

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

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

Large accelerated filer ☐
Non-accelerated filer ☒
Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol (s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	MBRX	The NASDAQ Stock Market LLC

The registrant had 28,444,425 shares of common stock outstanding at May 4, 2021.

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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 86,293	$ 15,173
Prepaid expenses and other current assets	1,726	2,025
Total current assets	88,019	17,198
Furniture and equipment, net	438	483
Intangible assets	11,148	11,148
Operating lease right-of-use asset	179	202
Total assets	$ 99,784	$ 29,031
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,928	$ 1,129
Accrued expenses and other current liabilities	2,650	1,791
Total current liabilities	4,578	2,920
Operating lease liability - long-term, net of current portion	127	159
Warrant liability - long-term	6,563	8,192
Total liabilities	11,268	11,271
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; 28,444,425 and 11,536,720 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	28	69
Additional paid-in capital	149,788	74,671
Subscription Receivable	—	(129)
Accumulated other comprehensive income	61	65
Accumulated deficit	(61,361)	(56,916)
Total stockholders' equity	88,516	17,760
Total liabilities and stockholders' equity	$ 99,784	$ 29,031

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,	
	2021	**2020**
Revenues	$ —	$ —
Operating expenses:		
Research and development	4,105	3,206
General and administrative	1,939	1,810
Depreciation and amortization	44	46
Total operating expenses	6,088	5,062
Loss from operations	(6,088)	(5,062)
Other income:		
Gain from change in fair value of warrant liability	1,577	3,845
Other income, net	9	5
Interest income, net	57	3
Net loss	$ (4,445)	$ (1,209)
Net loss per common share - basic and diluted	$ (0.20)	$ (0.15)
Weighted average common shares outstanding, basic and diluted	21,808,565	8,321,833
Net Loss	$ (4,445)	$ (1,209)
Other comprehensive income (loss):		
Foreign currency translation	(4)	(33)
Comprehensive loss	$ (4,449)	$ (1,242)

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,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (4,445)	$ (1,209)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	44	46
Stock-based compensation	405	397
Change in fair value of warrant liability	(1,577)	(3,845)
Operating lease, net	113	99
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	299	611
Accounts payable	799	(947)
Accrued expenses and other current liabilities	738	506
Net cash used in operating activities	(3,624)	(4,342)
Cash flows from investing activities:		
Purchase of fixed assets	—	(2)
Net cash used in investing activities	—	(2)
Cash flows from financing activities:		
Proceeds from exercise of warrants	63	—
Proceeds from sale of common stock, net of issuance costs	74,685	5,291
Net cash provided by financing activities	74,748	5,291
Effect of exchange rate changes on cash and cash equivalents	(4)	(33)
Net change in cash and cash equivalents	71,120	914
Cash and cash equivalents, at beginning of period	15,173	10,735
Cash and cash equivalents, at end of period	$ 86,293	$ 11,649
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ —	$ 6
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued liabilities	$ —	$ 23

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, 2021								
	Common Stock		Common Stock Subscribed						
	Shares	Par Value Amount	Shares	Par Value Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Subscription Receivable	Stockholder's Equity
Balance, December 31, 2020	11,536,720	$ 69	26,966	$ —	$ 74,671	$ (56,916)	$ 65	$ (129)	$ 17,760
Issuance of common stock, net of issuance costs of $6,159	16,883,420	18	(26,966)	—	74,537	—	—	129	74,684
Reverse stock split	14,285	(60)	—	—	60	—	—	—	—
Warrants exercised	10,000	1	—	—	115	—	—	—	116
Stock-based compensation	—	—	—	—	405	—	—	—	405
Consolidated net loss	—	—	—	—	—	(4,445)	—	—	(4,445)
Cumulative translation adjustment	—	—	—	—	—	—	(4)	—	(4)
Balance, March 31, 2021	28,444,425	$ 28	—	$ —	$ 149,788	$ (61,361)	$ 61	$ —	$ 88,516

	Three Months Ended March 31, 2020								
	Common Stock		Common Stock Subscribed						
	Shares	Par Value Amount	Shares	Par Value Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Subscription Receivable	Stockholders' Equity
Balance, December 31, 2019	7,621,338	$ 46	—	$ —	$ 55,055	$ (39,561)	$ 31	$ —	$ 15,571
Issuance of common stock, net of issuance costs of $709	1,250,000	7	—	—	559	—	—	—	566
Stock-based compensation	—	—	—	—	397	—	—	—	397
Consolidated net loss	—	—	—	—	—	(1,209)	—	—	(1,209)
Cumulative translation adjustment	—	—	—	—	—	—	(33)	—	(33)
Balance, March 31, 2020	8,871,338	$ 53	—	$ —	$ 56,011	$ (40,770)	$ (2)	$ —	$ 15,292

See accompanying notes to unaudited condensed consolidated financial statements.

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

1. Nature of Business

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. The Company's focus is on the treatment of highly resistant cancers and viruses through the development of its drug candidates. These candidates are based substantially on discoveries licensed from 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 perform certain preclinical development in Australia. This has enabled the Company to realize the benefits of certain research and development tax credits in Australia. In 2019, the Company sublicensed essentially all of the rights to its technologies in 29 countries in Europe and Asia to WPD Pharmaceuticals Sp.z o.o. (WPD or WPD Pharmaceuticals) in exchange for collaboration on development in Poland. Also in 2019, the Company sublicensed its technologies to Animal Life Sciences, Inc. (ALI), to enable research and commercialization for non-human use and share development data. As part of this agreement, ALI issued to the Company a 10% interest in ALI.

The Company has three core technologies: 1) Annamycin, which the Company refers to as a "next generation" anthracycline; 2) a portfolio of Immune/Transcription Modulators, of which WP1066 is one of the lead molecules; and 3) a portfolio of Metabolism/Glycosylation Inhibitors, of which WP1122 is the lead molecule. The Company has six drug candidates, representing all three core technologies, and three of which have shown human activity in clinical trials. As of the end of 2020, those three drug candidates accounted for five clinical trials in the United States (US) and Europe. Two of those trials are externally funded studies of WP1066 in brain tumors. Two internally funded Phase 1 clinical trials, Annamycin in acute myeloid leukemia (AML), and WP1220 in cutaneous T-cell lymphoma (CTCL), were successfully concluded. An additional Phase 1/2 clinical trial of Annamycin in AML is also internally funded and is currently ongoing. In 2021, the Company anticipates the initiation of four or more new clinical trials in addition to the three trials continuing from 2020.

In late 2020, MBI received US Food and Drug Administration (FDA) clearance to proceed with an additional Phase 1b/2 clinical trial of Annamycin for the treatment of soft tissue sarcoma (STS) lung metastases and the Company expects to commence this study in the US in the second half of 2021. Based on a recently announced reimbursement grant awarded in Poland, MBI expects a second Phase 1b/2 clinical trial of Annamycin in STS lung metastases to be primarily investigator-funded in Europe. MBI also plans to begin a Phase 1/2 clinical trial of Annamycin in combination with Ara-C for the treatment of AML in Europe, by seeking approval for its own clinical trial and a second, similar grant funded trial through its sublicensee, WPD Pharmaceuticals in Poland. The Company is also working with regulatory authorities in the United Kingdom (UK) to initiate a Phase 1 clinical trial of WP1122 in healthy volunteers with the intent to progress to COVID-19 patients either there or in locations where the prevalence of COVID-19 will adequately support recruitment. The Company intends to internally fund the initial trials of WP1122 but may seek external funding opportunities if activity is seen in COVID-19 patients. Additionally, the Company is pursuing filing an Investigative New Drug application (IND) in the US for the treatment of certain cancers in 2021. Finally, the Company continues to seek opportunities to collaborate on a potential Phase2 clinical study of WP1220 in CTCL.

The Company does not have manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, the Company does not have and does not intend to have a sales organization. The Company's overall strategy is to seek potential outlicensing opportunities with development/commercialization strategic partners who are better suited for the marketing, sales and distribution of its drugs if approved.

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 world. The spread of COVID-19 has caused significant volatility in US and international markets, including Poland, where MBI conducts some of its clinical trials and Italy, where its drug supply is produced. There has been limited interruption of its drug supply, and most Polish clinics where the Company is conducting trials are limiting access for monitoring activities. Additionally, MBI believes COVID- 19 has materially slowed the recruitment of patients for its clinical trials. This could worsen or be alleviated 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. Additionally, the Company believes that the potential for impact to its supply chain due to COVID-19 will be reduced as vaccine production normalizes throughout the industry. In light of current worldwide trends with respect to COVID-19, MBI does not expect COVID-19 to materially impact recruitment for current or future oncology trials as COVID-19 hospitalizations have recently decreased. However, the Company cannot be certain that these trends will continue and there is the possibility they may reverse.

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

Reverse Stock Split - On January 29, 2021, the Company filed a Certificate of Amendment to the amended and restated certificate of incorporation with the Secretary of State and the State of Delaware to effect a reverse stock split of all the issued and outstanding shares of the Company's common stock at a ratio of 1 for 6. The accompanying consolidated financial statements and notes to the consolidated financial statements gives retroactive effect to the reverse stock split for all periods presented. Certain amounts in the financial statements, the notes thereto, and elsewhere in the Form 10-Q may be slightly different than previously reported due to rounding up of fractional shares as a result of the reverse stock split.

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, 2020 and December 31, 2019 and notes thereto contained in the Form 10-K filed with the SEC on March 24, 2021.

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.

Significant Accounting Policies - The Company's significant accounting policies are described in Note 2, *Basis of Presentation, principles of consolidation and significant accounting policies*, to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. There have been no material changes to the significant accounting policies during the three months ended March 31, 2021, other than those noted below.

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.

Liquidity and Financial Condition - The Company is an early stage and emerging growth company (EGC) and has not generated any revenues to date. As such, the Company is subject to all of the risks associated with early stage and emerging growth companies. Since inception, the Company has incurred losses and negative cash flows from operating activities. For the three months ended March 31, 2021 and 2020, the Company incurred net losses of $4.4 million and $1.2 million, respectively, and had net cash flows used in operating activities of $3.6 million and $4.3 million, respectively. At March 31, 2021, the Company had an accumulated deficit of $61.4 million and cash and cash equivalents of $86.3 million. The Company expects its cash on hand as of March 31, 2021 will be sufficient to fund the Company's operations beyond the near term. Such projections are subject to changes in the Company's internally funded preclinical and clinical activities, including unplanned preclinical and clinical activity. The Company does not expect to experience positive cash flows from operating activities in the near future and anticipates incurring operating losses for the next few years as it supports the development of its core technologies to the point of generating revenue, most likely via outlicensing, and continues to invest in research and development for additional applications of the Company's core technologies and potentially increase its pipeline of drug candidates. The Company anticipates incurring operating losses for the next several years. If the Company needs to raise additional capital in order to continue to execute its business plan, there is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company. A failure to raise sufficient capital could adversely impact the Company's ability to achieve its intended business objectives and meet its financial obligations as they become due and payable.

Cash and Cash Equivalents - Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company maintains cash accounts principally at one financial institution in the US, which at times, may exceed the Federal Deposit Insurance Corporation's limit. The Company has not experienced any losses from cash balances in excess of the insurance limit. The Company's management does not believe the Company is exposed to significant credit risk at this time due to the financial condition of the financial institution where its cash is held.

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

The Company has categorized its assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy in accordance with U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3).

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

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

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

The following table provides liabilities reported at fair value and measured on a recurring basis at March 31, 2021 and December 31, 2020 (in thousands):

Description	Fair Value	Level 1	Level 2	Level 3
Fair value of warrant liability as of March 31, 2021:	$ 6,563	$ —	$ —	$ 6,563
Fair value of warrant liability as of December 31, 2020:	$ 8,192	$ —	$ —	$ 8,192

The table below (in thousands) of Level3 liabilities begins with the valuation as of the beginning of thefirst quarter and then is adjusted for the exercises that occurred during the first quarter of 2021 and adjusted for changes in fair value that occurred during thefirst quarter. The ending balance of the Level 3 financial instrument presented above represents the Company's best estimates and may not be substantiated by comparison to independent markets and, in many cases, couldnot be realized in immediate settlement of the instruments.

Three Months Ended March 31, 2021	Warrant Liability Long-Term	Warrant Liability Total
Balance, December 31, 2020	$ 8,192	$ 8,192
Exercise of warrants	(52)	(52)
Change in fair value - net	(1,577)	(1,577)
Balance, March 31, 2021	$ 6,563	$ 6,563

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, 2021 and 2020, approximately 3.8 million and approximately 3.1 million, respectively, of potentially dilutive shares were excluded from the computation of diluted earnings per share due to their antidilutive effect.

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 2020, the FASB issued ASU No. 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40) (ASU 2020-06). ASU 2020-06 simplifies the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of both liabilities and equity, including convertible instruments and contracts in an entity's own equity. The guidance is effective for the Company beginning on January 1, 2022 and prescribes different transition methods for the various provisions. 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 butnot 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, 2021	December 31, 2020
Accrued research and development	$ 1,299	$ 907
Accrued payroll and bonuses	810	426
Accrued legal, regulatory, professional and other	324	262
Operating lease liability - current	122	118
Accrued related party	95	78
Total accrued expenses and other current liabilities	$ 2,650	$ 1,791

Additionally, accounts payable includes $48,000 as of March 31, 2021 and December 31, 2020, respectively, for a related party payable.

4. Warrants

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.

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

	March 31, 2021	December 31, 2020
Risk-free interest rate	0.1% to 0.7%	0.1% to 0.3%
Volatility	96.5% to 136.1%	113.7% to 127.4%
Expected life (years)	0.9 to 4.5	1.1 to 4.6
Dividend yield	—%	—%

A summary of the Company's liability classified warrant activity during the three months ended March 31, 2021 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, 2021	2,733,645	$ 6.30	$ 16.80	$ 9.45	3.6
Granted	—	—	—	—	—
Exercised	(10,000)	6.30	6.30	6.30	—
Expired	—	—	—	—	—
Balance at March 31, 2021	2,723,645	$ 6.30	$ 16.80	$ 9.46	3.4
Exercisable at March 31, 2021	2,723,645	$ 6.30	$ 16.80	$ 9.46	3.4

For a summary of the changes in fair value associated with the Company's warrant liability for the three months ended March 31, 2021, see Note 2 - Basis of presentation, principles of consolidation and significant accounting policies - Fair Value of Financial Instruments.

Equity Classified Warrants

At March 31, 2021 and December 31, 2020, respectively, the Company had 109,639 equity classified warrants outstanding and 85,472 warrants were exercisable.

There was no stock compensation expense for non-employee agreements equity classified warrants for the three months ended March 31, 2021 and 2020, respectively and $124,000 of unrecognized stock compensation expense related to the Company's equity-classified warrants.

5. Equity

Q1 2021 Stock Issuances

In February 2021, the Company entered into an underwritten public offering for the sale by the Company of 14,273,684 shares of its common stock at a public offering price of $4.75 per share and granted the underwriters a 30-day option to purchase up to an additional 2,141,052 shares of common stock offered in the public offering, which was exercised. The Company received total proceeds of $78.0 million, prior to deducting the underwriting discount and other estimated offering expenses. In January 2021 the Company issued 468,684 shares for gross proceeds of $2.9 million using the Company's At The Market Agreement with Oppenheimer & Co., Inc. The Company terminated the 2020 ATM Agreement on February 2, 2021. Additionally, during the first quarter of 2021, 10,000 shares were issued due to the exercise of warrants related to past public offerings. Gross proceeds received due to these exercises approximated $63,000.

Q1 2020 Stock Issuances

In February 2020, the Company entered into subscription agreements with certain institutional investors for the sale by the Company of 1,250,000 shares of its common stock and warrants to purchase 937,501 shares of common stock at a combined public offering price of $4.80 per share and related warrant. The Company received total proceeds of $6.0 million, prior to deducting the placement agent fees and other offering expenses.

Stock-Based Compensation and Outstanding Awards

The 2015 Stock Plan provides for the grant of stock options, stock awards, stock unit awards, and stock appreciation rights. As of March 31, 2021, there were 726,493 shares remaining to be issued under the 2015 Stock Plan. The Company did not have any grants, exercises, or forfeitures of any stock-based awards during the three months ended March 31, 2021.

Stock-based compensation for the three months ended March 31, 2021 and 2020, respectively (in thousands):

	Three Months Ended March 31,	
	2021	2020
General and administrative	$ 309	$ 334
Research and development	96	63
Total stock-based compensation expense	$ 405	$ 397

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 2021 as a result of the losses recorded during the three months ended March 31, 2021 and the additional losses expected for the remainder of 2021 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, 2021, 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, 2021 and 2020, respectively. The effective tax rate for the three months ended March 31, 2021 and 2020 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.

7. Commitments and Contingencies

In addition to the commitments and contingencies described elsewhere in these notes, see below for a discussion of the Company's commitments and contingencies as of March 31, 2021.

Lease Obligations Payable

The following summarizes quantitative information about the Company's operating leases for the three months ended March 31, 2021 and 2020, respectively (in thousands):

	Three Months Ended March 31,	
	2021	2020
Lease cost:		
Operating lease cost	$ 29	$ 29
Variable lease cost	7	7
Short-term lease cost	—	4
Total	$ 36	$ 40

The Company recorded approximately $10,000 in sublease income from a related party for the three months ended March 31, 2021 and 2020, respectively. Sublease income is recorded as other income, net on the Company's condensed consolidated statement of operations and comprehensive loss. Operating cash flows from operating leases was $34,000 and $33,000 for the three months ended March 31, 2021 and 2020, respectively.

At March 31, 2021, 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, 2021
2021 (remaining nine months)	$ 104
2022	105
2023	56
2024	10
2025 and thereafter	—
Total lease payments	275
Less: imputed interest	(26)
Present value of operating lease liabilities	$ 249

As of March 31, 2021, the weighted average remaining lease term for operating leases is 2.2 years, and the weighted average discount rate is 9.6%. The interest rate implicit in lease contracts is typically not readily determinable and as such, the Company uses an incremental borrowing rate based on a peer analysis using information available at the commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Licenses

MD Anderson - Total expenses related to the Company's license agreements with MD Anderson were $38,000 and $61,000 for the three months ended March 31, 2021 and 2020, 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 $59,000 and $108,500 for the three months ended March 31, 2021 and 2020, respectively.

Sponsored Research Agreements with MD Anderson - MBI has a Sponsored Laboratory Study Agreement with MD Anderson expiring in October 2021. In February 2021, the Company extended this Agreement until December 31, 2022. The expenses recognized under this MD Anderson agreement with regards to the Sponsored Laboratory Study Agreements were $94,000 and $179,000 for the three months ended March 31, 2021 and 2020, respectively.

8. Subsequent Events

In addition to the subsequent events discussed elsewhere in these notes, see below for a discussion of the Company's subsequent events occurring after March 31, 2021.

The Company entered into an agreement, effective subsequent to March 31, 2021, with an investor relations consultant and as part of that agreement 5,000 shares of common stock will be issued in the aggregate between April 1, 2021 and December 31, 2021. Additionally, the Company entered to an advisory agreement on April 29, 2021 with a consultant, pursuant to which the Company issued a warrant to purchase 71,500 shares of common stock which will vest equally and quarterly over five years, or earlier upon a change of control, and only while services are being rendered.

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 success or the lack thereof, including the ability to recruit patients, of our clinical trials through all phases of clinical development;
- 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 impact of COVID-19 our clinical trials, clinical drug candidate supplies, preclinical activities and our ability to raise future financing;
- Our ability to continue our relationship with MD Anderson, including our ability to maintain current licenses and license future intellectual property resulting from our sponsored research agreements with MD Anderson;
- Our ability to obtain additional funding to commence or continue our clinical trials, fund operations and develop our product candidates;
- The need to obtain and retain regulatory approval of our drug candidates, both in the United States and 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;
- Potential efficacy of our drug candidates;
- 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;
- 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

We are a clinical stage pharmaceutical company focused on the treatment of highly resistant cancers and viruses. We have three core technologies, based substantially on discoveries made at M.D. Anderson Cancer Center (MD Anderson). These three core technologies are Annamycin, the WP1066 Portfolio, and the WP1122 Portfolio and include a total of six drug candidates, three of which have now shown human activity in clinical trials.

Three Core Technologies

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 (the efficacy of all currently approved anthracyclines is limited by both multidrug resistance and cardiotoxicity). WP1066 is one of several Immune/Transcription Modulators, designed to stimulate the immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs) while also inhibiting key oncogenic transcription factors, including p-STAT3 (phosphorylated signal transducer and activator of transcription 3), c-Myc (a cellular signal transducer named after a homologous avian virus called Myelocytomatosis) and HIF-1α (hypoxia inducible factor 1α). These transcription factors are widely sought targets that are believed to contribute to an increase in cell survival and proliferation, and the angiogenesis (coopting vasculature for blood supply), invasion, metastasis and inflammation associated with tumors. They may also play a role in the inability of immune checkpoint inhibitors to affect more resistant tumors. WP1220 is a close analog to WP1066 that we have developed as a potential topical therapy for skin-related diseases.

Our third core technology is centered on new compounds designed to target the roles of glycolysis and glycosylation in both cancer and viral diseases. As an example, 2-deoxy-D-glucose (2-DG) is a glucose decoy that is capable of inhibiting glycolysis, thereby cutting off the primary fuel supply for both cancer cells and viral host cells by taking advantage of their high level of dependence on glucose in comparison to healthy cells. In addition, 2-DG is capable of altering glycosylation, a process by which, when coopted by tumors, cancer cells are believed to evade the body's immune response. In the case of viruses like SARS-CoV-2 (the virus responsible for COVID-19), glycosylation forms the glycoprotein spikes surrounding the coronavirus that give it its name and enable both evasion of the immune response and the ability to infect new host cells. One of the limitations of 2-DG, however, is how rapidly it is metabolized, resulting in a short circulation time and limited 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. Recent published research has identified that 2-DG has antiviral potential against SARS-CoV-2 *in vitro* and, based on publicly available information, a recently completed Phase 2 clinical trial by an unrelated company in India has reported efficacy in COVID-19 patients, resulting in the Emergency Use Authorization of 2-DG by the Drugs Controller General of India. New research also points to the potential for 2-DG to be capable of enhancing the usefulness of checkpoint inhibitors. Considering that WP1122 generally outperforms 2-DG alone in both *in vitro* and *in vivo* tumor models and in viral *in vitro* models, we believe WP1122 has the opportunity to become an important drug to potentiate existing therapies, including checkpoint inhibitors. We are also engaged in preclinical development of additional antimetabolites (WP1096 and WP1097) targeting glycolysis and glycosylation.

Clinical Trials

During 2020, three of our drug candidates accounted for five clinical trials in the US and Europe. Two of those trials are ongoing externally funded studies of WP1066 in brain tumors. Two of our internally funded Phase 1 clinical trials have concluded. The US trial for Annamycin in acute myeloid leukemia (AML) successfully met its safety endpoint, and the trial for WP1220 in cutaneous T-cell lymphoma (CTCL) demonstrated an objective response rate of 45% and a clinical benefit rate of 100%. An additional Phase 1/2 clinical trial of Annamycin in AML is also internally funded and is currently ongoing. In 2021, we anticipate the initiation of four or more new clinical trials in addition to the three trials continuing from 2020.

Below we use certain terms to describe our clinical trials. By "internally funded" we mean that the primary costs of the preclinical activity and clinical trials are funded by us. “Externally funded” drug candidates include those for which preclinical work is funded and performed by external collaborators and for which clinical trials are physician sponsored. For externally funded research, any grant funds that support such preclinical work or clinical trials and most of the associated expenses are not reflected in our financial statements. However, the costs of drug product and other minor supporting activities that we provide for externally funded preclinical activities and clinical trials are included in our financial statements.

Recently reported data from our sponsored research demonstrates that in AML mouse models, the combination of Annamycin with Ara-C (a chemotherapy drug commonly used in AML patients) has a synergistic effect, suggesting that this combination may be more beneficial for AML patients than Annamycin as a single agent. Accordingly, we plan to begin a Phase 1/2 clinical trial of Annamycin in combination with Ara-C for the treatment of AML in Europe, by seeking approval for our own internally funded clinical trial in Europe and a second, similar trial through our sublicensee, WPD Pharmaceuticals, in Poland. Furthermore, we received U.S. Food and Drug Administration (FDA) clearance in late 2020 to proceed with a Phase 1b/2 clinical trial of Annamycin for the treatment of soft tissue sarcoma (STS) lung metastases and we are preparing to begin this internally funded trial in the US in the third quarter of 2021. Additionally, we expect in 2021 a second Phase 1b/2 clinical trial of Annamycin in sarcoma lung metastases to be primarily investigator-funded in Europe.

WP1066 is currently in two US physician-sponsored Phase 1 trials, one at MD Anderson for the treatment of glioblastoma (GBM) in adults and another at Emory University for the treatment of pediatric brain tumors (including DIPG and medulloblastoma). We began and completed a "proof-of-concept" Phase 1 clinical trial in 2020 in Poland for a third drug, WP1220 (a molecule in the WP1066 portfolio), for the topical treatment of cutaneous T-cell lymphoma (CTCL). We are actively seeking collaboration with a strategic partner in the near term for external funding for the continued development of WP1220 in a Phase 2 clinical trial as a topical therapy for CTCL, and based on the pace of current discussions, we do not anticipate this trial to begin this year. If we are not successful in this outreach, we may choose to use internal funds to generate additional human data to facilitate such outreach efforts.

Finally, we are also in discussions with regulatory authorities in the United Kingdom (UK) to initiate a Phase 1 clinical trial of WP1122 in healthy volunteers with the intent to progress to COVID-19 patients either there or in locations where the prevalence of COVID-19 will adequately support recruitment. We intend to internally fund the initial trials of WP1122 but may seek external funding opportunities. Additionally, we are planning to file an IND in the US for the treatment of certain cancers with WP1122.

In summary, we had five clinical trials underway or concluded in 2020 and we now expect up to seven or more clinical trials to be underway or approved in 2021, including externally funded trials.

Update on Clinical Trials and Licensing

Annamycin

Annamycin is currently in one Phase 1/2 clinical trial in Europe, and the Phase 1 portion of another Phase 1/2 AML trial in the US has been concluded, subject to final database lock and closure, which should occur in the third quarter of 2021.

The trial in Poland is in its fifth cohort, where patients are being treated at 240 mg/m2. Patient 2 in this cohort experienced certain elevated liver enzymes (AST and ALT), which under the current protocol, are considered a dose limiting toxicity (DLT). In this instance, the DLT was secondarily related to concomitant medication not being withheld. Although that DLT resolved, in accordance with the trial protocol, the cohort was expanded and has now enrolled a total of five patients. In March 2021, patient 4 in this cohort experienced a similar DLT, which also resolved. Although treatment was discontinued for Patients 2 and 4, a total of three patients in this cohort received the full dose of Annamycin without any DLTs and, based on preliminary data, all three responded to treatment, with one relapsed patient experiencing a complete response (CR), a refractory patient experiencing a partial response (PR) and another relapsed patient completely clearing circulating blasts. With this preliminary data, 40% of the patients being treated at 240 mg/m2 experienced clinical benefit. Combining these results with prior cohorts in Poland and with the cohorts in the US trial, six of seventeen relapsed AML patients or 35% experienced clinical benefit (CR, CRi, PR, or Bridge-To-Transplant). One refractory patient in the Poland trial experienced a PR.

Although the elevated liver enzymes described above meet the test of a “Dose Limiting Toxicity” per the clinical trial protocol, our medical advisors have determined that these instances were transient and self-limited with no evidence of serious sequalae (related longer-term negative effects) and, therefore, should not be considered DLTs in future patients unless these elevated enzyme levels do not return to near baseline (baseline or less than or equal to grade 1) within a reasonable time or if there is other evidence of serious sequalae. Based on this new data, we are planning to amend the protocol for this trial in Poland to change the DLT criteria as it relates to transient grade 3 elevations to allow us to dose three additional patients in the 240 mg/m2 cohort. If no DLT is experienced with these next three patients, we will escalate dosing in new cohorts by 30 mg/m2 instead of the 60 mg/m2 previously planned, and with a de-escalation of 15 mg/m2 at the DLT dose if future patients experience a DLT. We cannot provide any assurance that such an amendment will be approved.

Additionally, our sublicense partner, WPD Pharmaceuticals Sp.z o.o. (WPD), recently announced that it was conditionally awarded a reimbursement grant of approximately $6.7 million (20.4 million PLN) from the Polish National Center for Research and Development (“NCRD”), for the development of Annamycin. The funds will be used for the continued development of Annamycin, including a clinical trial of Annamycin in combination with Ara-C for which this grant is expected to cover the reimbursement of about 60% of planned costs. WPD is a sub-licensee of certain technologies from us in 29 countries in Europe and Asia. We expect that this trial will begin in 2021 but since this is an externally funded trial, we cannot provide any assurance regarding actual timing.

Regarding our planned US clinical trial of Annamycin for the treatment of STS lung metastases, we executed a clinical trial agreement with with Sarcoma Oncology Research Center, an institution in Santa Monica, CA to be the first clinical site. We expect this trial to begin in the third quarter of 2021.

Earlier in 2021, we announced that the Agencja Badań Medycznych (The Medical Research Agency) a Polish state agency responsible for development of scientific research in the field of medical and health sciences, awarded a grant equivalent to $1.5 million to the Maria Sklodowska-Curie National Research Institute to fund a Phase 1b/2 clinical trial of Annamycin for the treatment of STS lung metastases. The grant-funded clinical trial will be led by Prof. Piotr Rutkowski, MD, PhD, Head of Department of Soft Tissue/Bone Sarcoma and Melanoma at the Maria Sklodowska-Curie National Research Institute of Oncology in Warsaw, Poland. Prof. Piotr Rutkowski will be assisted, in part, by WPD who will provide support in preparation for and conduct of the clinical trial, which is expected to begin this year. As a part of the collaboration between Moleculin and Prof. Rutkowski, Moleculin will be supplying the drug product and other ancillary services necessary for the clinical trial, but Moleculin will not participate in conducting the clinical trial. This trial is independent from and will be in addition to the US clinical trial Moleculin is planning to conduct with Annamycin in STS lung metastases.

WP1066

The clinical trial of WP1066 for the treatment of adult brain tumors at MD Anderson has completed the fourth cohort at 8mg/kg in the dose escalation phase. In the first quarter of 2021, we were notified that the physician sponsoring this trial is leaving MD Anderson. As a result, MD Anderson has notified us that they will be closing this trial. Several additional institutions have expressed an interest in sponsoring similar research on WP1066 in brain tumors, so to help ensure the potential continuation of this important research, regardless of the sponsoring institution, we have requested the IND for this trial to be transferred into our name with the FDA, although we can provide no assurance as to when, or if, this transfer will be completed. While we are working to continue this research in additional physician-sponsored trials, we expect that continued research on WP1066 in adult GBM will be temporarily delayed in 2021.

Three patients have now been treated in the second cohort of the Phase 1 dose escalation portion of physician-sponsored clinical trial at Emory University for the treatment of pediatric brain tumors with WP1066 at the dose level of 6mg/kg and this dose has been deemed to be safe. Recruitment will now begin for the third cohort with dosing at 12 mg/kg.

WP1122

Based on previously announced data demonstrating the antiviral potential of our lead antimetabolite molecule, WP1122, we intend to test the drug candidate for the potential treatment of COVID-19. Although we have previously disclosed that antiviral clinical trials in the US will be dependent upon demonstrating efficacy in an appropriate COVID-19 animal model, we recently engaged in discussions with the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (UK) regarding the potential for beginning clinical trials of WP1122 without the need for additional preclinical animal efficacy models. Based on our initial discussions with the MHRA, we believe that a COVID-19 animal model will not be required in order to submit a clinical trial application (CTA) for a Phase 1 clinical trial beginning with healthy volunteers in that country, although no final determination has been made by the MHRA. Based on this feedback, we intend to proceed with the submission of a CTA for a Phase 1 clinical trial of WP1122 in the UK.

The preclinical work to evaluate molecules within the WP1122 portfolio of antimetabolites (which include molecules capable of inhibiting glycolysis and altering glycosylation) for viral indications is mostly similar to the preclinical work we originally planned as part of developing WP1122 for cancer indications. Accordingly, we believe the preclinical work we have completed for WP1122 will also support an IND application or its equivalent in other countries for cancer-related clinical trials. We continue to plan to submit such an IND in the US in 2021.

COVID-19 Impact on Clinical Trials

The spread of COVID-19 has caused significant volatility in US and international markets, including Poland, where we conduct some of our clinical trials, and Italy, where our drug supply is produced. There has been limited interruption of our drug supply, and most Polish clinics where we are conducting trials are limiting access for monitoring activities, which could delay our ability to collect data and authorize new patient recruitment. Additionally, we believe COVID-19 has materially slowed the ability of approved sites to recruit patients for our trials. This could worsen or be alleviated 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, we are unable to determine if it will have a material impact to our operations. Recently, we continue to experience a limited increase in activity with regard to recruitment of new patients in Poland. Additionally, we believe that the potential for impact to our supply chain due to COVID-19 has been reduced as vaccine production normalizes throughout the industry. Considering current worldwide trends with respect to COVID-19, we cannot determine whether COVID-19 will materially impact recruitment for current or future trials.

Licensing

We are currently in discussions with MD Anderson regarding amendments to existing licenses and new licenses related to Annamycin and WP1122.

Recent Business Developments

Below are recent business developments.

Annamycin

FDA Approval of Fast Track Designation for Annamycin in the Treatment of Sarcoma Lung Metastases

On March 30, 2021, we announced that the FDA had approved our request for Fast Track Designation for our drug, Annamycin, for the treatment of STS lung metastases.

WP1066

Awarded New Rare Pediatric Disease Designation from U.S. FDA for WP1066 for the Treatment of Ependymoma

On April 14, 2021, we announced that the FDA has granted Rare Pediatric Disease Designation (RPD) to our p-STAT3 inhibitor, WP1066, for the treatment of ependymoma.

WP1122

IQVIA to Manage Potential COVID-19 Clinical Trial

On April 6, 2021, we announced the engagement of IQVIA Biotech, a contract research organization (CRO) to manage our efforts to begin potential clinical trials of WP1122 for the treatment of COVID-19.

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,	
	2021	**2020**
Revenues	$ —	$ —
Operating expenses:		
Research and development	4,105	3,206
General and administrative	1,939	1,810
Depreciation and amortization	44	46
Total operating expenses	6,088	5,062
Loss from operations	(6,088)	(5,062)
Other income:		
Gain from change in fair value of warrant liability	1,577	3,845
Other income, net	9	5
Interest income, net	57	3
Net loss	$ (4,445)	$ (1,209)

Three Months Ended March 31, 2021 Compared to Three Months Ended March 31, 2020

Research and Development Expense. Research and development (R&D) expense was $4.1 million and $3.2 million for the three months ended March 31, 2021 and 2020, respectively. The increase of $0.9 million is mainly related to increased clinical trial activity as described above, increased costs related to sponsored research agreements and costs related to manufacturing of additional drug product.

General and Administrative Expense. General and administrative expense was $1.9 million and $1.8 million for the three months ended March 31, 2021 and 2020, respectively. The increase of $0.1 million is mainly related to an increase in our insurance, which was offset by a similar decrease in travel expenses.

Gain from Change in Fair Value of Warrant Liability. We recorded a net gain of $1.6 million in the first quarter of 2021 as compared to a net gain of $3.8 million in the first quarter of 2020, 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,	
	2021	**2020**
Net cash used in operating activities	$ (3,624)	$ (4,342)
Net cash used in investing activities	—	(2)
Net cash provided by financing activities	74,748	5,291
Effect of exchange rate changes on cash and cash equivalents	(4)	(33)
Net increase in cash and cash equivalents	$ 71,120	$ 914

As of March 31, 2021, there was $0.4 million of cash on hand in a bank account in Australia and we know of no related limitations impacting our liquidity in Australia.

Cash used in operating activities

Cash used in operations was $3.6 million for the three months ended March 31, 2021. This $0.7 million decrease over the prior year period of $4.3 million was primarily due to an increase in accounts payable, which was slightly offset by: 1) payments for developing, manufacturing and testing drug product as we prepared for clinical trials; 2) an increase in R&D contractor headcount and associated 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 provided in financing activities

In February 2021, we completed an underwritten public offering of an aggregate of 14,273,684 shares of common stock at a public offering price of $4.75 per share. We granted the underwriters a 30-day option to purchase up to an additional 2,141,052 shares of common stock offered in the public offering. The offering closed on February 5, 2021 and gross proceeds of the offering were approximately $67.8 million, prior to deducting the underwriting discount and other offering expenses. On February 10, 2021, the underwriters of the public offering exercised in full their option to purchase an additional 2,141,052 shares of common stock at the public offering price of $4.75 per share, bringing total gross proceeds to approximately $78.0 million before underwriting discount.

In January 2021 we issued 468,684 shares for gross proceeds of $2.9 million using our At The Market Agreement with Oppenheimer & Co., Inc. We terminated the ATM Agreement on February 2, 2021. Additionally, during the first quarter of 2021, 10,000 shares were issued due to the exercise of warrants related to past public offerings. Gross proceeds received due to these exercises approximated $63,000.

In February 2020, we entered into subscription agreements with institutional investors to purchase 1,250,000 shares of our common stock and warrants to purchase 937,501 shares of common stock at a combined public offering price of $4.80 per share and related warrant resulting in gross proceeds of $6.0 million. Each warrant has an exercise price of $6.30 per share and were exercisable six months from the date of issuance and will expire five years from the date they were first exercisable.

We believe that our existing cash and cash equivalents as of March 31, 2021 will be sufficient to meet our projected operating requirements, which include a forecasted increase over our current R&D rate of expenditures, through at least the year 2023. Such projections are subject to changes in our internally funded preclinical and clinical activities, including unplanned preclinical and clinical activity. We anticipate incurring operating losses for the next several years as we support the preclinical and clinical activities necessary to prepare our drug candidates for successful out licensing, including our efforts to expand our technologies. These factors raise uncertainties about our ability to fund operations in future years. If we need to raise additional capital in order to continue to execute our business plan, there is no assurance that additional financing will be available when needed or that we will be able to obtain financing on terms acceptable to us. A failure to raise sufficient capital could adversely impact our ability to achieve our intended business objectives and meet our financial obligations as they become due and payable.

Critical Accounting Policies and Significant Judgments and Estimates

There have been no material changes to our critical accounting policies and use of estimates from those disclosed in our Form 10-K for the year ended December 31, 2020. For a discussion of our critical accounting policies and use of estimates, refer to Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Estimates in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2020.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

Not applicable 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), who is our principal executive officer, and Chief Financial Officer (CFO), who is our principal financial and accounting officer, 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 effective as of March 31, 2021.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15-d-15(f) under the Exchange Act) during the three months ended March 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Our employees are working remotely due to the COVID-19 pandemic, but we do not believe that our adjustments to how we work have materially impacted our internal controls over financial reporting. We continue to monitor and assess the potential impact of the COVID-19 pandemic 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, 2020. 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, 2020 as filed with the SEC.

Changes to the patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our future drugs and our drug candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents that we license or hold directly. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Recent patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a first-to-file system. The first-to-file provisions, however, only become effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition, there have been recent proposals for additional changes to the patent laws of the U.S. and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. In recent years, many such changes have been made and changes are likely to continue to occur in the future. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders', tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability. The impact of these and other future changes in tax laws is uncertain and could have an adverse effect on our business, cash flow, financial condition or results of 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.

None.

ITEM 6. EXHIBITS

Exhibit No.	Description
3.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Moleculin Biotech, Inc., filed with the Secretary of State of the State of Delaware (incorporated by reference to exhibit 3.1 of the Company's Form 8-K filed January 29, 2021)
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*	Inline XBRL Instance Document (the Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* 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 12, 2021

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

Date: May 12, 2021

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 12, 2021

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 12, 2021

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, 2021 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Walter V. 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 12, 2021

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, 2021 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan P. 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 12, 2021

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.