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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 September 30, 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 **77007**
(Address of principal executive offices) (Zip Code)

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

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

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

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

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

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

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

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

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

The registrant had 28,577,088 shares of common stock outstanding at November 3, 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)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 75,178	$ 15,173
Prepaid expenses and other current assets	1,892	2,025
Total current assets	77,070	17,198
Furniture and equipment, net	353	483
Intangible assets	11,148	11,148
Operating lease right-of-use asset	131	202
Total assets	$ 88,702	$ 29,031
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,390	$ 1,129
Accrued expenses and other current liabilities	2,266	1,791
Total current liabilities	3,656	2,920
Operating lease liability - long-term, net of current portion	75	159
Warrant liability - long-term	3,712	8,192
Total liabilities	7,443	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; 28,577,088 and 11,536,720 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	29	69
Additional paid-in capital	151,175	74,671
Subscription Receivable	—	(129)
Accumulated other comprehensive income	39	65
Accumulated deficit	(69,984)	(56,916)
Total stockholders' equity	81,259	17,760
Total liabilities and stockholders' equity	$ 88,702	$ 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,095	4,435	11,239	10,971
General and administrative	2,021	1,659	6,394	5,122
Depreciation and amortization	41	57	130	154
Total operating expenses	6,157	6,151	17,763	16,247
Loss from operations	(6,157)	(6,151)	(17,763)	(16,247)
Other income:				
Gain from change in fair value of warrant liability	1,678	2,743	4,428	1,489
Other income, net	13	10	30	32
Interest income, net	87	3	236	10
Net loss	$ (4,379)	$ (3,395)	$ (13,069)	$ (14,716)
Net loss per common share - basic and diluted	$ (0.15)	$ (0.33)	$ (0.50)	$ (1.55)
Weighted average common shares outstanding, basic and diluted	28,573,476	10,245,810	26,302,638	9,496,585
Net Loss	$ (4,379)	$ (3,395)	$ (13,069)	$ (14,716)
Other comprehensive income (loss):				
Foreign currency translation	(16)	10	(26)	2
Comprehensive loss	$ (4,395)	$ (3,385)	$ (13,095)	$ (14,714)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (13,069)	$ (14,716)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	130	154
Stock-based compensation	1,817	1,265
Change in fair value of warrant liability	(4,428)	(1,489)
Operating lease, net	102	90
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	133	294
Accounts payable	261	(810)
Accrued expenses and other current liabilities	361	565
Net cash used in operating activities	(14,693)	(14,647)
Cash flows from investing activities:		
Purchase of fixed assets	—	(360)
Net cash used in investing activities	—	(360)
Cash flows from financing activities:		
Proceeds from exercise of warrants	63	5
Payment of tax liability for vested restricted stock units	(24)	(17)
Proceeds from sale of common stock, net of issuance costs	74,685	17,077
Net cash provided by financing activities	74,724	17,065
Effect of exchange rate changes on cash and cash equivalents	(26)	2
Net change in cash and cash equivalents	60,005	2,060
Cash and cash equivalents, at beginning of period	15,173	10,735
Cash and cash equivalents, at end of period	$ 75,178	$ 12,795
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ 11	$ 20
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued liabilities	$ —	$ 316

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30, 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
Issuance of common stock in connection with equity purchase agreement, net of issuance costs of $403	107,788	1	—	—	—	—	—	—	1
Subscription of common stock in connection with Consulting Agreement	—	—	2,500	—	10	—	—	(10)	—
Stock-based compensation	—	—	—	—	433	—	—	—	433
Consolidated net loss	—	—	—	—	—	(4,244)	—	—	(4,244)
Cumulative translation adjustment	—	—	—	—	—	—	(6)	—	(6)
Balance, June 30, 2021	28,552,213	$ 29	2,500	$ —	$ 150,231	$ (65,605)	$ 55	$ (10)	$ 84,700
Issuance of common stock in connection with Consulting Agreement	3,750	—	(2,500)	—	(10)	—	—	10	—
Common stock issued upon vesting of restricted stock units (net of shares withheld for payment of tax liability)	21,125	—	—	—	(23)	—	—	—	(23)
Stock-based compensation	—	—	—	—	977	—	—	—	977
Consolidated net loss	—	—	—	—	—	(4,379)	—	—	(4,379)
Cumulative translation adjustment	—	—	—	—	—	—	(16)	—	(16)
Balance, September 30, 2021	28,577,088	$ 29	—	$ —	$ 151,175	$ (69,984)	$ 39	$ —	$ 81,259

	Nine Months Ended September 30, 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
Issued for cash - sale of common stock, net of issuance costs of $336	1,195,162	7	—	—	10,000	—	—	—	10,007
Warrants exercised	750	—	—	—	9	—	—	—	9
Stock-based compensation	—	—	—	—	408	—	—	—	408
Consolidated net loss	—	—	—	—	—	(10,112)	—	—	(10,112)
Cumulative translation adjustment	—	—	—	—	—	—	25	—	25
Balance, June 30, 2020	10,067,250	$ 60	—	$ —	$ 66,428	$ (50,882)	$ 23	$ —	$ 15,629
Issued for cash - sale of common stock, net of issuance costs of $135	216,855	2	—	—	1,778	—	—	—	1,780
Common stock issued upon vesting of restricted stock units (net of shares withheld for payment of tax liability)	9,990	—	—	—	(17)	—	—	—	(17)
Stock-based compensation	—	—	—	—	460	—	—	—	460
Consolidated net loss	—	—	—	—	—	(3,395)	—	—	(3,395)
Cumulative translation adjustment	—	—	—	—	—	—	10	—	10
Balance, September 30, 2020	10,294,095	$ 62	—	$ —	$ 68,649	$ (54,277)	$ 33	$ —	$ 14,467

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 July 2021, MBI formed Moleculin Amsterdam B.V., a wholly owned subsidiary, primarily to act as its legal representative for clinical trials in Europe for Moleculin Biotech, Inc.

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 a minimum amount of externally funded collaboration on development in Europe over a certain amount of time. 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 five drug candidates, representing all three core technologies, and three of those 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 (U.S.) 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 internally funded Phase 1/2 clinical trial of Annamycin in AML is currently ongoing in Poland. In the second quarter of 2021, the Company commenced enrollment and dosed the first subject in its U.S. Phase 1b/2 clinical trial evaluating Annamycin for the treatment of soft tissue sarcoma (STS) lung metastases. Enrollment in that trial is also ongoing. The Company anticipates that the externally funded WP1066 trial in brain tumors at MD Anderson will be terminated this year and expects to commence a similar WP1066 externally funded trial elsewhere in 2022.

Additionally, MBI expects a second, grant funded Phase 1b/2 clinical trial of Annamycin in STS lung metastases to be primarily investigator-funded in Poland. 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, possibly, a second, similar grant funded trial through its sublicensee, WPD Pharmaceuticals in Poland. In October 2021, the Company received authorization from regulatory authorities in the United Kingdom (U.K.) to commence a Phase 1a 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 encouraging activity is seen in COVID-19 patients. Additionally, the Company is pursuing filing an Investigative New Drug application (IND) in the U.S. with WP1122 for the treatment of certain cancers prior to the end of 2021. Finally, the Company continues to seek opportunities to collaborate on a potential Phase 2 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 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 and Worldwide Supply Chain Issues - 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 U.S. and international markets, including Poland, where MBI conducts some of its clinical trials and Italy, where its Annamycin 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 materially slowed the recruitment of patients for its clinical trials, but it is now beginning to see an increase in recruitment. 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 U.S. 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 the third quarter, worldwide supply chain issues began delaying certain shipments. The supply chain for the manufacturing of the Company's drug candidates and supplies for clinical trials can be complicated and involves several parties. If the Company were to experience any supply chain issues, including as a result of the COVID-19 pandemic, the Company's product supply could be disrupted. The Company believes that its operations have not been materially impacted to date. In view of current worldwide trends with respect to COVID-19 and worldwide supply chain issues, MBI does not expect either issue to materially further impact recruitment for or the operation of current or future clinical trials. 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 give 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 U.S. (U.S. GAAP) for financial information, and in accordance with the rules and regulations of the U.S. 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 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 subsidiaries. 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 U.S.

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 nine months ended September 30, 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 nine months ended September 30, 2021 and 2020, the Company incurred net losses of $13.1 million and $14.7 million, respectively, and had net cash flows used in operating activities of $14.7 million and $14.6 million, respectively. At September 30, 2021, the Company had an accumulated deficit of $70.0 million and cash and cash equivalents of $75.2 million. The Company expects its cash on hand as of September 30, 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. 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 U.S., 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 September 30, 2021 and December 31, 2020 (in thousands):

Description	Fair Value	Level 1	Level 2	Level 3
Fair value of warrant liability as of September 30, 2021:	$ 3,712	$ —	$ —	$ 3,712
Fair value of warrant liability as of December 31, 2020:	$ 8,192	$ —	$ —	$ 8,192

The table below of Level 3 liabilities (in thousands) begins with the valuation as of the beginning of the third quarter and then is adjusted for changes in fair value that occurred during the third 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, could not be realized in immediate settlement of the instruments.

Three Months Ended September 30, 2021	Warrant Liability Long-Term	Warrant Liability Total
Balance, June 30, 2021	$ 5,390	$ 5,390
Change in fair value - net	(1,678)	(1,678)
Balance, September 30, 2021	$ 3,712	$ 3,712

The table below of Level 3 liabilities (in thousands) begins with the valuations as of December 31, 2020 and is adjusted for the exercises and for changes in fair value that occurred during the nine months ended September 30, 2021. 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, could not be realized in immediate settlement of the instruments.

Nine Months Ended September 30, 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	(4,428)	(4,428)
Balance, September 30, 2021	$ 3,712	$ 3,712

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 September 30, 2021 and 2020, approximately 4.5 millionand approximately 3.8 million, respectively, of potentially dilutive shares were excluded from the computation of diluted earnings per share due to their antidilutive effect. For the nine months ended September 30, 2021 and 2020, approximately 4.1 million and 3.4 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 of these unaudited condensed consolidated financial statements. See notes and specifically Note 8 - Subsequent Events.

Recent Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or 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 consolidated financial statements.

In May 2021, the FASB issued ASU No. 2021-04, Earnings Per Share (Topic 260), Debt - Modifications and Extinguishments (Subtopic 470-50), Compensation - Stock Compensation (Topic 718), and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. ASU 2021-04 clarifies certain aspects of the current guidance to promote consistency among reporting of an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted for all entities, including adoption in an interim period. The Company is currently evaluating the potential impact this standard will have, if any, on its consolidated 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):

	September 30, 2021	December 31, 2020
Accrued research and development	$ 1,322	$ 907
Accrued legal, regulatory, professional and other	459	262
Accrued payroll and bonuses	350	426
Operating lease liability - current	115	118
Accrued related party	20	78
Total accrued expenses and other current liabilities	$ 2,266	$ 1,791

Additionally, accounts payable includes $48,000 as of September 30, 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 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 U.S. 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 Black-Scholes option pricing model 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:

	September 30, 2021	December 31, 2020
Risk-free interest rate	0.0% to 0.7%	0.1% to 0.3%
Volatility	41.2% to 123.1%	113.7% to 127.4%
Expected life (years)	0.4 to 3.9	1.1 to 4.6
Dividend yield	—%	—%

A summary of the Company's liability classified warrant activity during the nine months ended September 30, 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 September 30, 2021	2,723,645	$ 6.30	$ 16.80	$ 9.46	2.9
Exercisable at September 30, 2021	2,723,645	$ 6.30	$ 16.80	$ 9.46	2.9

For a summary of the changes in fair value associated with the Company's warrant liability for the nine months ended September 30, 2021, see Note 2 - Basis of presentation, principles of consolidation and significant accounting policies - Fair Value of Financial Instruments.

Equity Classified Warrants

In April 2021, the Company granted equity-classified warrants to purchase 71,500 shares of common stock with a five-year term and an exercise price of $3.63 vesting quarterly over five years while services are being performed. In August 2021, the Company entered into a portfolio development advisory agreement with a related party entity and in connection with the agreement, the Company granted equity-classified warrants to purchase 250,000 shares of common stock with a ten-year term and an exercise price of $3.08. The August 2021 warrants vest as follows: (a) 50% vests upon execution of the agreement, provided the advisor does not terminate the agreement prior to the end of the one-year term; and (b) 50% vests 60 days after the end of the one-year term, subject to the Company's Board of Directors determining that the services provided have been adequately performed. Also, both the April 2021 and August 2021 warrants vest in full if there is a change of control event, as defined in the agreement.

At September 30, 2021, the Company had 396,502 equity classified warrants outstanding and 182,985 warrants were exercisable. At December 31, 2020, the Company had 109,639 equity classified warrants outstanding and 85,472 warrants were exercisable.

The Company recorded stock compensation expense for equity classified warrants of $422,000 and zero for the three months ended September 30, 2021 and 2020, respectively, and $432,000 and $5,000 during the nine months ended September 30, 2021 and 2020, respectively. At September 30, 2021, there was $632,000 of unrecognized stock compensation expense related to the Company's equity classified warrants.

5. Equity

2021 Stock Issuances

In June 2021, the Company entered into an At Market Issuance Sales Agreement (2021 ATM Agreement) with Oppenheimer & Co. Inc. Pursuant to the terms of the 2021 ATM Agreement, the Company may offer and sell, from time to time through Oppenheimer shares of the Company's common stock with an aggregate sales price of up to $50.0 million. As of the date of this report, there have been no issuances under the 2021 ATM Agreement.

In June 2021, the Company entered into a Purchase Agreement with Lincoln Park Capital Fund. Pursuant to the terms of the Purchase Agreement, Lincoln Park agreed to purchase from the Company up to $20.0 million of common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, at the time the Company signed the Purchase Agreement, the Company issued 107,788 shares of common stock to Lincoln Park as an initial fee for its commitment to purchase shares of the Company's common stock under the Purchase Agreement, and has agreed to issue Lincoln Park up to an additional 53,893 shares of common stock as commitment shares pro-rata when and if Lincoln Park purchases (at our discretion) the $20.0 million aggregate commitment. The initial commitment shares issued in June 2021 were valued at $0.4 million, recorded as an addition to equity for the issuance of common stock and treated as a reduction to equity as a cost of capital to be raised under the Purchase Agreement. There have been no additional shares issued to date under this agreement.

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 2020 At The Market Agreement (2020 ATM Agreement) with Oppenheimer & Co., Inc. The Company terminated the 2020 ATM Agreement on February 2, 2021.

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 September 30, 2021, there were 43,628 shares remaining to be issued under the 2015 Stock Plan.

Stock-based compensation for the three and nine months ended September 30, 2021 and 2020, respectively (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
General and administrative	$ 443	$ 366	$ 1,085	$ 1,029
Research and development	534	94	732	236
Total stock-based compensation expense	$ 977	$ 460	$ 1,817	$ 1,265

During the nine months ended September 30, 2021, the Company granted 532,865 stock options with a weighted average fair value of $3.24 per share at the date of grant and 150,000 shares of restricted stock units with a weighted average fair value of $3.73 per share at the date of grant. These stock options have a weighted average exercise price of $3.75 per share and vest over a one to three-year period from the grant date on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in substance, multiple awards. These restricted stock units vest annually in four equal installments.

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 and nine months ended September 30, 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 September 30, 2021 and December 31, 2020 the Company maintained a full valuation allowance for all deferred tax assets.

The Company recorded no income tax provision for the three and nine months ended September 30, 2021 and 2020, respectively. The effective tax rate for the nine months ended September 30, 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 September 30, 2021.

Lease Obligations Payable

The following summarizes quantitative information about the Company's operating leases for the three and nine months ended September 30, 2021 and 2020, respectively (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Lease cost:				
Operating lease cost	$ 29	$ 29	$ 87	$ 87
Variable lease cost	7	7	22	22
Short-term lease cost	—	4	—	13
Total	$ 36	$ 40	$ 109	$ 122

The Company recorded approximately $10,000 and $31,000 in sublease income from a related party for the three and nine months ended September 30, 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$35,000 and $34,000 for the three months ended September 30, 2021 and 2020, respectively, and $103,000 and $100,000 for the nine months ended September 30, 2021 and 2020, respectively.

Licenses

MD Anderson - Total expenses related to the Company's license agreements with MD Anderson were$56,000 and $61,000 for the three months ended September 30, 2021 and 2020, respectively, and$150,000 and $183,000 for the nine months ended September 30, 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 of $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 for the three months ended September 30, 2021 and 2020, respectively, and$176,000and $226,000 for the nine months ended September 30, 2021 and 2020, respectively.

Sponsored Research Agreements with MD Anderson - MBI has a Sponsored Laboratory Study Agreement with MD Anderson expiring December 31, 2022. In July 2021, the Company amended its Sponsored Laboratory Study Agreement with MD Anderson for total payment of $175,000 to support the continuation of the project. The expenses recognized under this MD Anderson agreement with regards to the Sponsored Laboratory Study Agreements were $220,000 and $212,000 for the three months ended September 30, 2021 and 2020, respectively, and$498,000 and $537,000 for the nine months ended September 30, 2021 and 2020, respectively.

8. Subsequent Events

There were no additional subsequent events occurring after September 30, 2021 except those discussed elsewhere in these notes.

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:

- 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;
- 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 on our clinical trials, clinical drug candidate supplies, preclinical activities 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;
- The need to obtain and retain regulatory approval of our drug candidates, both in the United States and in Europe, 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 five 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 potential 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 U.S. 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 U.S. 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 have initiated two additional clinical trials and we anticipate the initiation of two or more new clinical trials in addition to the three trials continuing from 2020, as discussed further below. The brain tumor trial at MD Anderson will be terminated this year, as the original lead physician investigator moved to another institution, and we expect a new, similar externally funded trial to begin elsewhere in 2022.

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/or 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, and as one of the possible trials to be initiated mentioned above in 2021, 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 possibly 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 began this internally funded trial in the U.S. in the second 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 U.S. 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). The brain tumor trial at MD Anderson will be terminated this year and we expect a new, similar externally funded trial to begin elsewhere in 2022. 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 received authorization from regulatory authorities in the United Kingdom (U.K.) to commence a Phase 1a 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 U.S. 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 six clinical trials to be underway or approved in 2021, including externally funded trials, with more expected to begin in 2022.

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 U.S. has been concluded, subject to final database closure, which should occur prior to the end 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 original clinical trial protocol, were 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 partial response, a refractory patient experiencing a partial response (PR) and another relapsed patient completely clearing circulating blasts. With this preliminary data, 67% of the patients receiving a full course of treatment at 240 mg/m2 experienced clinical benefit. It is also noteworthy that the patient with a PR was refractory to prior induction therapy and, as such, a response to single agent therapy is generally not expected.

Although the elevated liver enzymes described above meet the test of a “Dose Limiting Toxicity” per the original 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 amended the protocol for this trial in Poland to change the DLT criteria as it relates to transient grade 3 elevations of liver enzymes to allow us to dose three additional patients in the 240 mg/m2 cohort. This amendment was approved and granted allowance by regulatory authorities in Poland in July 2021. 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. As of the end of October, one of the three patients needed to complete the cohort was admitted to the trial and began dosing.

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 may be used for the continued development of Annamycin, including a possible 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 plan to commence a similar trial combining Annamycin with Ara-C for the treatment of AML prior to the end of 2021 and possibly prior to this grant funded trial starting. The grant-funded trial should begin in the near term and since this is an externally funded trial subject to ongoing granting authority oversight, we cannot provide any assurance as to when or if it will commence.

Regarding our ongoing U.S. clinical trial of Annamycin for the treatment of STS lung metastases, we currently have three sites open and active in the study and expect a total of five sites to be active by the first quarter of 2022. In the second quarter of 2021 this trial began enrolling and dosing patients. The three sites open are as follows: 1) Sarcoma Oncology Research Center in Santa Monica, CA; 2) Rutgers, The State University in New Brunswick, NJ; and 3) Washington University in St. Louis, MO.

On August 12, 2021, we announced that patients were treated in the first cohort at a dose level of 210 mg/m^2 with no drug-related adverse events constituting a dose limiting toxicity (DLT) during the 21-day DLT evaluation period, including no signs of cardiotoxicity. The results for all three patients were reviewed in the Cohort Review Meeting, which determined that the trial could progress to the next higher dose level of 270 mg/m^2.

On October 18, 2021, we announced that the second cohort had concluded safely and that the next cohort at the next higher dose level of 330 mg/m^2 would open. Additionally, we reported that four of the five patients that have completed scans to date (from cohort one and two) demonstrated a response to treatment, including three with extended and, in one case, continuing stable disease and one patient with a substantial (>30%) reduction in tumor size, constituting a PR under the protocol. The third cohort was opened the following week and one patient has enrolled and started treatment. Two other patients have been identified. Further updates on patients will be announced at the end of the third cohort.

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 before the end of the first quarter of 2022. As this is a grant funded trial, we have limited input and control over timing. 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 U.S. clinical trial Moleculin is planning to conduct with Annamycin in STS lung metastases. As an important point of differentiation, the clinical protocol for the Polish trial provides for a different dosing regimen than the U.S. trial.

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 would be leaving MD Anderson. As a result, and as expected, 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 right to reference the MD Anderson IND, as provided for under our Clinical Trial Agreement with MD Anderson, in our own IND. We are working to continue this research in additional physician-sponsored trials in 2022.

One patient has been treated in the third 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 8mg/kg. Two more patients will be treated at this dose level. Emory University has amended its protocol to allow dosing at 16 mg/kg after these two additional patients have been dosed, and the third cohort dosing has been deemed safe.

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 U.S. will be dependent upon demonstrating efficacy in an appropriate COVID-19 animal model, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (U.K.) is not making such animal data a requirement for a clinical trial application (CTA) for a Phase 1a clinical trial beginning with healthy volunteers in that country. Based on their feedback, in August 2021 we submitted a CTA for a Phase 1a clinical trial of WP1122 for the treatment of COVID-19 in the U.K. On October 19, 2021, we announced that we received authorization from regulatory authorities in the U.K. to commence a Phase 1a 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.

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 U.S. in 2021.

COVID-19 and Worldwide Supply Chain Issues

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 U.S. and international markets, including Poland, where we conduct some of our clinical trials and Italy, where our Annamycin 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. Additionally, we believe COVID-19 materially slowed the recruitment of patients for our clinical trials, but we are now beginning to see an increase in recruitment. 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 U.S. and international economies and, as such, we are unable to determine if it will have a material impact to our operations. Additionally, we believe that the potential for impact to our supply chain due to COVID-19 will be reduced as vaccine production normalizes throughout the industry. In the third quarter, worldwide supply chain issues began delaying certain shipments. The supply chain for the manufacturing of our drug candidates and supplies for clinical trials can be complicated and involves several parties. If we were to experience any supply chain issues, including as a result of the COVID-19 pandemic our product supply could be disrupted. We believe that our operations have not been materially impacted to date. In view of current worldwide trends with respect to COVID-19 and worldwide supply chain issues, we do not expect either issue to materially further impact recruitment for or the operation of current or future clinical trials. However, we cannot be certain that these trends will continue and there is the possibility they may reverse.

We receive requests for compassionate use (or its foreign equivalent) of our drug candidates in the ordinary course of business. WP1066 and Annamycin have both been involved with such requests. As we have very limited involvement in the treatment of such patients, we do not ordinarily report the details on such uses.

Licensing

We are currently in discussions with MD Anderson regarding amendments to existing licenses and new licenses related to Annamycin and WP1122 and expect to execute the related amendments and new licenses by the end of 2021. In the second quarter, we amended the WP1122 license to allow for an additional six-month extension to file a U.S. IND for the application of WP1122 until February 2022 on the condition that we file a similar application in another country. On August 3, 2021, we filed a CTA for the application of WP1122 in the United Kingdom, which filing satisfied one of the requirements under the license agreement. In addition, we intend to file a U.S. IND for the application of WP1122 before the end of 2021, which will satisfy the remaining IND filing requirement. We retain the right to further extend these dates within the amended agreement.

Recent Business Developments

Below are recent business developments.

Annamycin

Interim Data in Phase 1b/2 Clinical Trial of Annamycin for the Treatment of Soft Tissue Sarcoma Lung Metastases

On October 18, 2021, we announced the interim and preliminary data from the first two cohorts evaluating Annamycin for the treatment of soft tissue sarcoma lung metastases. The data demonstrated 80% clinical activity, defined as stable disease or better. We have noted that no DLT's have been experienced to-date, including cardiotoxicity. Patient enrollment in third cohort began subsequently.

Approval to Extend Dose Escalation in Phase 1/2 European Clinical Trial Evaluating Annamycin for the Treatment of Acute Myeloid Leukemia

On July 13, 2021, we announced that we had received approval from the Bioethics Committee of the Medical University of Karol Marcinkiewicz in Poznań (Ethics Committee) as well as an allowance from the Polish Department of Registration of Medicinal Products (URPL) for a protocol amendment for our Phase 1/2 evaluating Annamycin for the treatment of subjects with acute myeloid leukemia (AML) that is refractory to or relapsed after induction therapy.

First Subject Enrolled and Dosed in Phase 1b/2 Clinical Trial of Annamycin for the Treatment of Sarcoma Lung Metastases

On June 21, 2021, we announced that we commenced enrollment and dosed the first subject in our U.S. Phase 1b/2 clinical trial evaluating Annamycin for the treatment of STS lung metastases.

Receives Clearance to Commence Phase 1b/2 Clinical Trial of Annamycin for the Treatment of Sarcoma Lung Metastases

On May 25, 2021, we announced that we received clearance to initiate our Phase 1b/2 clinical trial evaluating Annamycin for the treatment of STS lung metastases. We announced that the first of several planned clinical sites was open and we expected to begin patient enrollment.

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 soft tissue sarcoma.

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 had granted Rare Pediatric Disease Designation (RPD) to our p-STAT3 inhibitor, WP1066, for the treatment of ependymoma, one of the four unique indications for which WP1066 now has RPD status.

WP1122

Receives Authorization from the Medicines and Healthcare Products Regulatory Agency (MHRA) to Commence Phase 1a Clinical Trial of WP1122 for the Treatment of COVID-19

On October 19, 2021, we announced that we received authorization from the MHRA to commence a Phase 1a clinical trial of WP1122 in the United Kingdom. We also announced we received a favorable opinion from the London - Riverside Research Ethics Committee in the U.K. to begin the study, which is expected to be conducted at the Medicines Evaluation Unit in Manchester, United Kingdom.

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.

Corporate

Inclusion in the Russell 2000 Index

On June 15, 2021, we announced that as part of the annual reconstitution of the Russell stock indexes, we were selected to be added to the Russell 2000 Index effective after the close of the U.S. equity markets on June 25, 2021.

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,095	4,435	11,239	10,971
General and administrative	2,021	1,659	6,394	5,122
Depreciation and amortization	41	57	130	154
Total operating expenses	6,157	6,151	17,763	16,247
Loss from operations	(6,157)	(6,151)	(17,763)	(16,247)
Other income:				
Gain from change in fair value of warrant liability	1,678	2,743	4,428	1,489
Other income, net	13	10	30	32
Interest income, net	87	3	236	10
Net loss	$ (4,379)	$ (3,395)	$ (13,069)	$ (14,716)

Three Months Ended September 30, 2021 Compared to Three Months Ended September 30, 2020

Research and Development Expense. Research and development (R&D) expense was $4.1 million and $4.4 million for the three months ended September 30, 2021 and 2020, respectively. The decrease of $0.3 million is mainly related to the timing of costs incurred in 2020 of producing additional drug product for Annamycin clinical trials.

General and Administrative Expense. General and administrative expense was $2.0 million and $1.7 million for the three months ended September 30, 2021 and 2020, respectively. The increase of $0.3 million is mainly related to an increase in consulting and advisory fees and an increase in our corporate insurance.

Gain from Change in Fair Value of Warrant Liability. We recorded a net gain of $1.7 million in the third quarter of 2021 as compared to a net gain of $2.7 million in the third 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.

Nine Months Ended September 30, 2021 Compared to Nine Months Ended September 30, 2020

Research and Development Expense. Research and development (R&D) expense was $11.2 million and $11.0 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of $0.2 million is mainly related to increased clinical trial activity as described above, and costs related to manufacturing of additional drug product.

General and Administrative Expense. General and administrative expense was $6.4 million and $5.1 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of $1.3 million is mainly related to an increase in consulting and advisory fees and an increase in our corporate insurance.

Gain from Change in Fair Value of Warrant Liability. We recorded a net gain of $4.4 million in the third quarter of 2021 as compared to a net gain of $1.5 million in the third 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):

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	$ (14,693)	$ (14,647)
Net cash used in investing activities	—	(360)
Net cash provided by financing activities	74,724	17,065
Effect of exchange rate changes on cash and cash equivalents	(26)	2
Net increase in cash and cash equivalents	$ 60,005	$ 2,060

As of September 30, 2021, there was $0.3 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 $14.7 million for the nine months ended September 30, 2021. This $0.1 million increase over the prior year period of $14.6 million was primarily due to payments for increased consulting and advisory fees as well as an increase in our corporate insurance. 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 June 2021, we entered into an At Market Issuance Sales Agreement (2021 ATM Agreement) with Oppenheimer & Co. Inc. Pursuant to the terms of the 2021 ATM Agreement, we may offer and sell, from time to time through Oppenheimer shares of our common stock with an aggregate sales price of up to $50.0 million. As of the date of this report, there have been no issuances under the 2021 ATM Agreement.

In June 2021, we entered into a Purchase Agreement with Lincoln Park Capital Fund (Lincoln Park Agreement). Pursuant to the terms of the Purchase Agreement, Lincoln Park agreed to purchase from us up to $20.0 million of common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, at the time we signed the Purchase Agreement, we issued 107,788 shares of common stock to Lincoln Park as an initial fee for its commitment to purchase shares of our common stock under the Purchase Agreement, and have agreed to issue Lincoln Park up to an additional 53,893 shares of common stock as commitment shares pro-rata when and if Lincoln Park purchases (at our discretion) the $20.0 million aggregate commitment.

To date, we have not used the 2021 ATM Agreement nor the Lincoln Park Agreement to raise additional capital beyond what is described above.

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 2020 ATM Agreement with Oppenheimer & Co., Inc. We 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.

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.

In April 2020, we issued 1,195,162 shares of common stock at an average price of $8.65 per share pursuant to the 2020 ATM Agreement. We received total proceeds of $10.3 million, prior to deducting transaction expenses. Additionally, during the second quarter of 2020, 750 shares were issued due to the exercise of warrants related to past public offerings. Gross proceeds received due to these exercises approximated $5,000.

In July 2020, we issued 216,855 shares of common stock at an average price of $8.82 per share through the ATM Prospectus Supplement. We received total proceeds of $1.9 million, net of $0.1 million in transaction expenses.

We believe that our existing cash and cash equivalents as of September 30, 2021 will be sufficient to meet our projected operating requirements, which include a forecasted increase over our current R&D rate of expenditures, into the year 2024. 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 September 30, 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 nine months ended September 30, 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, and in Part II, Item 1A in our prior quarterly reports on Form 10-Q filed during this fiscal year. 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 and in our prior quarterly reports on Form 10-Q filed during this fiscal year, each as filed with the SEC.

We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we or any manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. In addition, the supply chain for the manufacturing of our product candidates is complicated and can involve several parties. If we were to experience any supply chain issues, including as a result of the COVID-19 pandemic, our product supply could be seriously disrupted.

Shareholder activism could cause material disruption to our business.

Publicly traded companies have increasingly become subject to campaigns by activist investors advocating corporate actions such as actions related to environment, social and governance (ESG) matters, among other issues. Responding to proxy contests and other actions by such activist investors or others in the future could be costly and time-consuming, disrupt our operations and divert the attention of our Board of Directors and senior management from the pursuit of our business strategies, which could adversely affect our results of operations and financial condition.

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
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: November 10, 2021

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

Date: November 10, 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.

November 10, 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.

November 10, 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 September 30, 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: November 10, 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 September 30, 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: November 10, 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.