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, 2019
or
☐TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission File Number: 001-37758

MOLECULIN BIOTECH, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

The registrant had 45,727,700 shares of common stock outstanding at November 8, 2019.

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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 15,409	$ 7,134
Prepaid expenses and other current assets	3,177	840
Total current assets	18,586	7,974
Furniture and equipment, net	358	463
Intangible assets	11,148	11,148
Operating lease right-of-use asset	306	—
Total assets	$ 30,398	$ 19,585
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,188	$ 1,246
Accrued expenses and other current liabilities	1,111	2,452
Warrant liability - current	6,820	180
Total current liabilities	11,119	3,878
Operating lease liability - long-term, net of current portion	304	—
Deferred rent - long-term	—	107
Warrant liability - long-term	—	1,328
Total liabilities	11,423	5,313
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 and 75,000,000 shares authorized as of September 30, 2019 and December 31, 2018, 45,727,700 and 28,528,663 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	46	29
Additional paid-in capital	54,673	40,564
Accumulated other comprehensive income	19	35
Accumulated deficit	(35,763)	(26,356)
Total stockholders' equity	18,975	14,272
Total liabilities and stockholders' equity	$ 30,398	$ 19,585

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,	
	2019	**2018**	**2019**	**2018**
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	2,785	1,332	7,816	6,801
General and administrative	1,672	1,248	4,748	3,859
Depreciation and amortization	51	11	147	27
Total operating expenses	4,508	2,591	12,711	10,687
Loss from operations	(4,508)	(2,591)	(12,711)	(10,687)
Other income (expense):				
Gain from change in fair value of warrant liability	124	573	3,059	1,614
Other income (expense)	5	(21)	5	(23)
Interest income, net	5	1	10	5
Net loss before taxes	(4,374)	(2,038)	(9,637)	(9,091)
Income tax benefit	229	—	229	—
Net loss	$ (4,145)	$ (2,038)	$ (9,408)	$ (9,091)
Net loss per common share - basic and diluted	$ (0.09)	$ (0.08)	$ (0.24)	$ (0.36)
Weighted average common shares outstanding: Basic and diluted	45,464,746	26,861,497	39,034,303	25,373,634
Net Loss	$ (4,145)	$ (2,038)	$ (9,408)	$ (9,091)
Other comprehensive income (loss):				
Foreign currency translation	(3)	15	(16)	21
Comprehensive loss	$ (4,148)	$ (2,023)	$ (9,424)	$ (9,070)

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,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (9,408)	$ (9,091)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	147	27
Stock-based compensation	1,155	825
License rights expense settled in stock	490	—
Gain from change in fair value of warrant liability	(3,059)	(1,614)
Operating lease, net	(10)	—
Loss on foreign currency transactions	—	23
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,337)	(172)
Accounts payable	1,942	(25)
Accrued expenses and other current liabilities	(1,441)	923
Other long-term liabilities	—	11
Net cash used in operating activities	(12,521)	(9,093)
Cash flows from investing activities:		
Purchase of fixed assets	(42)	(303)
Net cash used in investing activities	(42)	(303)
Cash flows from financing activities:		
Proceeds from exercise of stock options	5	—
Proceeds from exercise of warrants	1,557	15
Proceeds from sale of common stock, net of issuance costs	19,292	10,269
Net cash provided by financing activities	20,854	10,284
Effect of exchange rate changes on cash and cash equivalents	(16)	$ (2)
Net change in cash and cash equivalents	8,275	886
Cash and cash equivalents, at beginning of period	7,134	7,714
Cash and cash equivalents, at end of period	$ 15,409	$ 8,600
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 1	$ 3
Cash paid for taxes	$ 15	$ 20
Property and equipment in accrued liabilities	$ 21	$ 136
Leasehold improvements paid by landlord	$ —	$ 82
Research and development expense settled in stock	$ 490	$ —

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Stockholders' Equity
Balance, December 31, 2018	28,528,663	$ 29	$ 40,564	$ (26,356)	$ 35	$ 14,272
Issued for cash - sale of common stock, net of issuance costs of $617	5,250,000	5	3,221	—	—	3,226
Issued to Lincoln Park - sale of common stock	605,367	—	883	—	—	883
Stock options exercised	25,000	—	5	—	—	5
Stock-based compensation	—	—	348	—	—	348
Consolidated net loss	—	—	—	(4,041)	—	(4,041)
Cumulative translation adjustment	—	—	—	—	(11)	(11)
Balance, March 31, 2019	34,409,030	$ 34	$ 45,021	$ (30,397)	$ 24	$ 14,682
Issued for cash - sale of common stock, net of issuance costs of $1,300	9,375,000	9	3,575	—	—	3,584
Warrants exercised	1,413,018	2	4,729	—	—	4,731
Stock-based compensation	—	—	318	—	—	318
Consolidated net loss	—	—	—	(1,221)	—	(1,221)
Cumulative translation adjustment	—	—	—	—	(2)	(2)
Balance, June 30, 2019	45,197,048	$ 45	$ 53,643	$ (31,618)	$ 22	$ 22,092
Issued to Lincoln Park - sale of common stock, net of issuance costs of $59	100,674	—	52	—	—	52
Common stock issued for license rights	429,978	1	489	—	—	490
Stock-based compensation	—	—	489	—	—	489
Consolidated net loss	—	—	—	(4,145)	—	(4,145)
Cumulative translation adjustment	—	—	—	—	(3)	(3)
Balance, September 30, 2019	45,727,700	$ 46	$ 54,673	$ (35,763)	$ 19	$ 18,975

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Stockholders' Equity
Balance, December 31, 2017	21,469,109	$ 21	$ 31,577	$ (14,480)	$ —	$ 17,118
Warrants exercised	9,752	—	15	—	—	15
Issued for cash - sale of common stock, net of issuance costs of $809	4,290,000	5	5,117	—	—	5,122
Stock-based compensation	—	—	242	—	—	242
Consolidated net loss	—	—	—	(1,927)	—	(1,927)
Balance, March 31, 2018	25,768,861	$ 26	$ 36,951	$ (16,407)	$ —	$ 20,570
Issued for cash - sale of common stock, net of issuance costs of $232	1,092,636	1	957	—	—	958
Stock-based compensation	—	—	339	—	—	339
Consolidated net loss	—	—	—	(5,125)	—	(5,125)
Cumulative translation adjustment	—	—	—	—	6	6
Balance, June 30, 2018	26,861,497	$ 27	$ 38,247	$ (21,532)	$ 6	$ 16,748
Stock-based compensation	—	—	244	—	—	244
Consolidated net loss	—	—	—	(2,038)	—	(2,038)
Cumulative translation adjustment	—	—	—	—	15	15
Balance, September 30, 2018	26,861,497	$ 27	$ 38,491	$ (23,570)	$ 21	$ 14,969

See accompanying notes to unaudited condensed consolidated financial statements.

1. Nature of Business and Liquidity

The terms "MBI" or "the Company", "we", "our", and "us" are used herein to refer to Moleculin Biotech, Inc. MBI is a clinical-stage pharmaceutical company, organized as a Delaware corporation in July 2015, with its focus on the treatment of highly resistant cancers via the development of its oncology drug candidates, all of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center, which we refer to as MD Anderson. MBI formed Moleculin Australia Pty. Ltd., (MAPL), a wholly owned subsidiary in June 2018, to begin preclinical development in Australia for WP1732, an analog of WP1066. This enables the Company to enjoy the benefits of certain research and development tax credits in Australia. In February 2019, the Company entered into an agreement with Animal Life Sciences, LLC ("ALI"), where the Company has granted a sublicense to ALI to research, develop, make, have made, use, offer to sell, sell, export or import and commercialize certain licensed products for non-human use and share development data. ALI issued to the Company a 10% interest in ALI. ALI converted into a corporation and became Animal Life Sciences, Inc.

Core Technologies - MBI has three core technologies with six drug candidates, all of which are based on discoveries made at MD Anderson. These core technologies are 1) Annamycin, 2) its STAT3 Immune/Transcription Modulators, or simply "Immune/Transcription Modulators" WP1066 portfolio and 3) its Metabolism/Glycosylation Inhibitor portfolio, WP1122. The Company's clinical stage drugs are Annamycin, an anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML and WP1066, an Immune/Transcription Modulator targeting brain tumors, pancreatic cancer and AML. We have completed full enrollment and begun treating patients with WP1220, an analog of WP1066, for the topical treatment of cutaneous T-cell lymphoma ("CTCL"), a form of skin cancer, in a clinical trial approved by Polish regulators in January 2019. MBI is also engaged in preclinical development of additional drug candidates, including other Immune/Transcription Modulators, as well as Metabolism/Glycosylation Inhibitors. With the approval of the Polish clinical trial in January 2019 for WP1220 for the treatment of CTCL, the Company now has three drugs in four clinical trials.

The Company believes Annamycin is a "Next Generation Anthracycline" since it is designed to avoid the multidrug resistance mechanisms that typically defeat currently approved anthracyclines, as well as to be non-cardiotoxic, which is the dose limiting toxicity of all currently approved anthracyclines. Annamycin is currently in two Phase I/II clinical trials, and preliminary clinical data suggests that it may have the potential to become the first therapy suitable for the majority of relapsed or refractory AML patients regardless of gene mutations. Additionally, preclinical research in animal models at MD Anderson demonstrated that Annamycin is able to significantly improve survival in an aggressive form of triple negative breast cancer metastasized to the lungs. Coupled with research demonstrating that Annamycin is capable of accumulating in the lungs at very high levels, this suggests that Annamycin may be well suited to become a treatment for lung-localized tumors.

WP1066 is one of several Immune/Transcription Modulators that appear capable of stimulating immune response to tumors by inhibiting the errant activity of Regulatory T-Cells ("TRegs") while also inhibiting key oncogenic transcription factors, including p-STAT3, c-Myc and HIF-1α. These transcription factors are widely sought targets that may also play a role in the lack of efficacy of immune checkpoint inhibitors in certain resistant tumors.

The Company is also developing new prodrugs to exploit the potential uses of inhibitors of glycolysis and glycosylation. Its lead Metabolism/Glycosylation Inhibitor compound, WP1122, provides an opportunity to cut off the fuel supply of tumors by taking advantage of their overdependence on glucose as compared with healthy cells. New research also points to the potential for the glucose decoy ("2-DG") within WP1122 to be capable of enhancing the usefulness of checkpoint inhibitors.

Drug Candidates - Within the Company's core technologies, it currently has six drug candidates representing three substantially different approaches to treating cancer. Annamycin is a chemotherapy designed to inhibit the replication of DNA of rapidly dividing cells and is the Company's most mature drug candidate. Annamycin had been in clinical trials pursuant to an investigational new drug application or IND that had been filed with the FDA. Due to a lack of development activity by a prior drug developer, this IND was terminated. To permit the renewed investigation of Annamycin, the Company resubmitted a new IND for a Phase I/II trial for the treatment of relapsed or refractory AML in August 2017, which the FDA allowed to go into effect in September 2017. The Company has trials open in the US and Poland and is actively recruiting in both countries.

The Company has five other drug development projects, two of which are also in clinical trials:

- WP1066 has an approved physician-sponsored clinical trial open for enrollment and dosing patients for the treatment of brain tumors and is also being evaluated for another physician-sponsored clinical trial for the potential treatment of pediatric brain tumors, as well as AML and pancreatic cancer,
- WP1220 is an analog of WP1066 for which Polish authorities in January 2019 approved the Company's Clinical Trial Application ("CTA") to study the topical treatment of CTCL, which study reached full enrollment in August 2019,
- WP1732, another analog of WP1066, is being evaluated along with WP1066 for the potential treatment of AML, pancreatic and other cancers, and MBI has begun pre-clinical work that it expects to generate sufficient data for an IND for an intravenous formulation of one of its STAT3 inhibitors, which filing is expected to be submitted in 2021, and
- WP1122 and WP1234 are being evaluated for their potential to treat brain tumors and pancreatic cancer via their ability to inhibit glycolysis.

Clinical Trials - The Company believes that patient recruitment for its Annamycin clinical trial in the US has been slow due to the high number of competitive clinical trials, combined with the FDA's requirement to set the initial dose level relatively low in comparison with previous Annamycin clinical trials. Additionally, the Company believes that patient recruitment for its clinical trial in Poland has been more successful than in the US due to a comparatively lower number of competitive clinical trials and the protocol there being approved to start at a significantly higher dose than in the US with fewer enrollment screening limitations.

In September 2018, the physician sponsored WP1066 Phase I clinical trial for the treatment of glioblastoma and melanoma metastasized to the brain, which opened for recruitment in July 2018, began treating patients.

In August 2019, the Company completed full enrollment in a proof-of-concept clinical trial in Poland to study WP1220, a part of the WP1066 portfolio, for the treatment of CTCL. Polish authorities approved the Company's CTA for this use in January 2019, and the trial began enrolling patients in March 2019.

Licenses - The Company has been granted royalty-bearing, worldwide, exclusive licenses for the patent and technology rights related to all of MBI's drug technologies, as these intellectual property rights are owned in part or entirely by MD Anderson. The Annamycin drug substance is no longer covered by any existing patent protection, however, the Company filed new patent applications in July 2019 for formulation, synthetic process and reconstitution related to MBI's Annamycin drug product candidate, although there is no assurance that the Company will be successful in obtaining such patent protection. Such technology is also licensed from MD Anderson. Independently from potential patent protection, MBI has received Orphan Drug designation ("ODD") from the FDA for Annamycin for the treatment of AML and for WP1066 for the treatment of glioblastoma. ODD may provide tax and other benefits during product development, and if either product is approved, may lead to a grant of seven-year market exclusivity. Under that exclusivity, which runs from the date of the approval of the New Drug Application ("NDA") in the United States, the FDA generally (there are important exceptions) could not approve another product containing the same drug for the designated indication. The Company also intends to apply for similar status in the European Union ("EU") where market exclusivity could extend to 10 years from the date of Marketing Authorization Application ("MAA") approval. Separately, the FDA may also grant market exclusivity of 5 years for newly approved new chemical entities (which the Company believes Annamycin would be one), which would preclude approval of any other annamycin product, but there can be no assurance that such exclusivity will be granted. In April 2019, FDA approved the Company's request for Fast Track Designation for Annamycin for the treatment of relapsed or refractory AML. Fast Track Designation, the purpose of which is to expedite drug development and approval, is granted to drugs intended to treat serious conditions and where data demonstrate the potential to address an unmet medical need.

Moleculin, LLC - Prior to MBI's initial public offering, the Company acquired Moleculin, LLC which was merged with and into MBI. Moleculin, LLC was the holder of a license agreement with MD Anderson covering technology referred to as the WP1066 Portfolio, which is focused on the modulation of key oncogenic transcription factors.

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

Basis of Presentation – Unaudited Interim Condensed Consolidated Financial Information - The accompanying unaudited interim condensed consolidated financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for financial information, and in accordance with the rules and regulations of the United States Securities and Exchange Commission (the "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, 2018 and December 31, 2017 and notes thereto contained in the Form 10-K filed with the SEC on February 21, 2019.

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

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

Going Concern - These condensed consolidated financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The continuation of the Company as a going concern is dependent upon the ability of the Company to obtain necessary equity financing to continue operations and the attainment of profitable operations. As of September 30, 2019, the Company has incurred an accumulated deficit of $35.8 million since inception and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of September 30, 2019, is sufficient to fund its planned operations into but not beyond the near term. These factors raise substantial doubt regarding the Company's ability to continue as a going concern. These unaudited condensed consolidated financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements and delay planned cash outlays or a combination thereof. Management cannot be certain that such events or a combination thereof can be achieved.

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

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

	September 30, 2019	December 31, 2018
Vendor prepayments and deposits	$ 1,994	$ 238
Prepaid insurance	560	171
Non-trade receivables	316	56
Other	307	375
Total prepaid expenses and other current assets	$ 3,177	$ 840

Vendor prepayments includes approximately $1.7 million for the expansion of Annamycin production commitments on a commercial scale to be delivered in 2020, which will be used in clinical trials.

Intangible Assets - Intangible assets with finite lives are amortized using the straight-line method over their estimated period of benefit. If an intangible asset is identified as an in-process research & development ("IPR&D") asset, then no

amortization will occur until the development is complete. If the associated research and development effort is abandoned, the related assets will be written-off and the Company will record a noncash impairment loss on its statements of operations. For those compounds that reach commercialization, if any, the IPR&D assets will be amortized over their estimated useful lives.

The Company evaluates the recoverability of intangible assets periodically and takes into account events or circumstances that warrant revised estimates of useful lives or that indicate that impairment exists. No material impairments of intangible assets have been identified during any of the periods presented. Intangible assets are tested for impairment on an annual basis, and between annual tests if the Company believes indicators of potential impairment exist, using a fair-value-based approach.

Property and Equipment, net - Leasehold improvements, furniture, equipment and software are recorded at cost and are depreciated using the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the shorter of the estimated useful life or the remaining lease term. Accumulated depreciation on property and equipment was $0.2 million at September 30, 2019, and $0.1 million at December 31, 2018.

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

Cost Method Investment - Our cost method investment consists of an investment in a private company in which we do not have the ability to exercise significant influence over its operating and financial activities. The investment is tested for impairment quarterly.

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

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. In the accompanying interim condensed consolidated financial statements as of September 30, 2019, the fair value of this warrant liability is included in current liabilities for the February 2017 Issuance of Warrants, the February 2018 Issuance of Warrants, the June 2018 Issuance of Warrants, the March 2019 Issuance of Warrants, and the April 2019 Issuance of Warrants. Warrant liabilities will be shown as a current liability on the balance sheet when it is deemed more probable than not by management to be exercised within one year.

The following table provides assets and liabilities reported at fair value and measured on a recurring basis at September 30, 2019 and at December 31, 2018 (in thousands):

Description	Liabilities Measured at Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Fair value of warrant liability as of September 30, 2019:	$ 6,820	$ —	$ —	$ 6,820
Fair value of warrant liability as of December 31, 2018:	$ 1,508	$ —	$ —	$ 1,508

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

Three Months Ended September 30, 2019	Warrant Liability Current	Warrant Liability Long-Term	Warrant Liability Total
Balance, June 30, 2019	$ 6,944	$ —	$ 6,944
Reclass of liability from long-term to current	—	—	—
Exercise of warrants	—	—	—
Issuances of warrants	—	—	—
Change in fair value - net	(124)	—	(124)
Balance, September 30, 2019	$ 6,820	$ —	$ 6,820

The table below (in thousands) of Level 3 liabilities begins with the valuation as of December 31, 2018 and then is adjusted for the issuances and exercises, and changes in fair value that occurred during the nine months ended September 30, 2019. The ending balance of the Level 3 financial instrument presented above represents our best estimates and may not be substantiated by comparison to independent markets and, in many cases, could not be realized in immediate settlement of the instruments.

Nine Months Ended September 30, 2019	Warrant Liability Current	Warrant Liability Long-Term	Warrant Liability Total
Balance, December 31, 2018	$ 180	$ 1,328	$ 1,508
Reclass of liability from long-term to current	1,328	(1,328)	—
Exercise of warrants	(3,174)	—	(3,174)
Issuances of warrants	11,545	—	11,545
Change in fair value - net	(3,059)	—	(3,059)
Balance, September 30, 2019	$ 6,820	$ —	$ 6,820

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 subject to vesting and warrants to purchase common stock were 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, 2019 and 2018,

approximately 14.7 million and approximately 6.5 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, 2019 and 2018, approximately 11.3 million and approximately 5.0 million, respectively, of potentially dilutive shares were excluded from the computation of diluted earnings per share due to their antidilutive effect.

Reclassifications - A reclassification was made to the prior period financial statements to conform to the 2019 presentation. Such reclassification did not affect net loss as previously reported. Historically, "Deferred compensation - related party" was a separate line item on the balance sheet. Management believes that this balance is best shown included in "accrued expenses and other current liabilities," and, as such, a reclassification was made to the balance sheet for the period ended December 31, 2018 to include "deferred compensation - related party" in with "accrued liabilities and other current liabilities." Additionally, interim disclosures pertaining to stockholders' equity are shown for current and comparative year-to-date periods, with subtotals for each interim period.

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

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). Under ASU 2016-02, an entity will be required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. ASU 2016-02 offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. For public companies, ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. In July 2018, the FASB issued ASU No. 2018-11, Leases Targeted Improvements ("ASU 2018-11"). In March 2019, the FASB issued ASU. No. 2019-01, Leases ("ASU 2019-01"). ASU 2019-01 and 2018-11 assists stakeholders with implementation questions and issues as organizations prepare to adopt the new leases standard. The Company adopted this standard on January 1, 2019 and used the effective date of initial application using the modified retrospective transition method. Upon adoption there was no cumulative-effect adjustment to the opening balance of retained earnings as of January 1, 2019. Therefore, prior period financial information has not been adjusted and continues to be reflected in accordance with the Company's historical accounting policy. The standard establishes a ROU asset model that requires the lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. (see Note 7. Commitments and Contingencies - Lease Obligations Payable).

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718) Improvements to Non-employee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 affects all entities that enter into share-based payment transactions for acquiring goods and services from non-employees. The amendments in this ASU expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The amendments in this ASU are effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption permitted, but no earlier than an entity's adoption date of Topic 606. The adoption of this pronouncement did not have a material impact on the Company's condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820) ("ASU 2018-13"). ASU 2018-13 modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement, based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of this ASU. The Company is currently evaluating the impact that this standard will have, if any, on its financial statements.

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

3. Accrued Expenses and Other Current Liabilities

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

	September 30, 2019	December 31, 2018
Accrued clinical testing	$ 349	$ 95
Accrued payroll and bonuses	249	492
Accrued other	144	227
Accrued legal and professional fees	137	91
Operating lease liability - current	100	—
Accrued license fees and sponsored research agreements	91	1,147
Accrued drug manufacturing costs	41	400
Total accrued expenses and other current liabilities	$ 1,111	$ 2,452

4. Warrant Liability

As of September 30, 2019, the Company had 10,256,193 warrants outstanding consisting of 5,250,000 warrants issued in April 2019; 1,585,500 warrants issued in March 2019; 742,991 warrants issued in June 2018; 2,273,700 warrants issued in February 2018; and 404,002 warrants issued in February 2017.

A summary of the Company's warrant activity during the nine months ended September 30, 2019 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, 2019	3,426,711	$ 1.50	$ 2.80	$ 2.48	4.53
Granted	8,242,500	$ 1.10	$ 1.75	$ 1.51	—
Exercised	(1,413,018)	$ 1.10	$ 1.50	$ 1.10	—
Expired	—	$ —	$ —	$ —	—
Balance at September 30, 2019	10,256,193	$ 1.10	$ 2.80	$ 1.89	4.29
Vested and Exercisable at September 30, 2019	10,256,193	$ 1.10	$ 2.80	$ 1.89	4.29

As discussed in Note 5, in connection with the offering that closed on April 25, 2019, the Company issued warrants to purchase 4,687,500 shares of its common stock (each a "Warrant"). The warrants are immediately exercisable at a price of $1.75 per share and expire five years from the date of issuance. In connection with the offering, the Company issued Oppenheimer & Co. Inc. a warrant (the "Underwriter Warrant") to purchase up to 562,500 shares of its common stock with an exercise price of $1.75 per share. The Underwriter Warrant expires on April 23, 2024.

As discussed in Note 5, in connection with the offering that closed on March 29, 2019, the Company issued warrants to purchase 2,625,000 shares of its common stock (each a "Warrant"). The warrants are immediately exercisable at a price of $1.10 per share, subject to adjustment in certain circumstances, and expire five years from the date of issuance. In connection with the offering, the Company issued Oppenheimer & Co. Inc. a warrant (the "Underwriter Warrant") to purchase up to 367,500 shares of its common stock with an exercise price of $1.10 per share. The Underwriter Warrant expires on March 27, 2024.

The basis of value of the warrant liability is fair value, which is defined pursuant to Accounting Standards Codification ("ASC") 820 to be "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date". The Company uses the Black-Scholes option pricing model ("BSM") to determine the fair value of its remaining warrants outstanding.

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. Where appropriate, the Company used the historical volatility of peer entities combined with the Company's due to the lack of sufficient historical data of its stock price during the years 2017 to 2019.

The assumptions used in the BSM models for its outstanding warrants are as follows:

	Nine Months Ended September 30, 2019		Year Ended December 31, 2018		
Risk-free interest rate	1.55 %	to 1.60 %	2.46 %	to	2.51 %
Volatility	90.00 %	to 97.50 %	75.00 %	to	80.00 %
Expected life (years)	2.37	to 4.57	3.12	to	4.98
Dividend yield	—%		—%		

5. Equity

The Company is authorized to issue 105,000,000 shares of which 5,000,000 shares of preferred stock are authorized and 100,000,000 shares of common stock are authorized.

Preferred Stock

The Company is authorized to issue up to 5,000,000 shares of preferred stock. Its certificate of incorporation authorizes the board to issue these shares in one or more series, to determine the designations and the powers, preferences and relative, participating, optional or other special rights and the qualifications, limitations and restrictions thereof, including the dividend rights, conversion or exchange rights, voting rights (including the number of votes per share), redemption rights and terms, liquidation preferences, sinking fund provisions and the number of shares constituting the series. As of September 30, 2019, there was no preferred stock issued.

Common Stock

Lincoln Park Transaction

On October 4, 2018, the Company entered into a purchase agreement (the "Purchase Agreement") and a registration rights agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from the Company up to $20.0 million of our common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement. Pursuant to the terms of the Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, at the time the Company signed the Purchase Agreement and the Registration Rights Agreement, the Company issued 243,013 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement and the Company may issue an additional 121,507 commitment shares pro-rata when and if Lincoln Park purchases (at the Company's discretion) the $20.0 million aggregate commitment. The commitment shares were valued at $337,788, 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. During the three months ended December 31, 2018, the Company issued 1,399,153 shares to Lincoln Park which included 10,918 commitment shares, for $1.8 million. During the first quarter of 2019, the Company issued 605,367 shares, which included 5,367 commitment shares for $0.9 million. No shares were issued to Lincoln Park during the second quarter of 2019. During the third quarter of 2019, the Company issued 100,674 shares to Lincoln Park which included 674 commitment shares, for $0.1 million.

At Market Issuance Sales Agreements ("ATM")

In September 2017, the Company entered into an At Market Issuance Sales Agreement (the “ATM Agreement”) with Roth Capital Partners, LLC ("Roth") and National Securities Corporation ("National") (collectively, the “Agents”). Pursuant to the terms of the ATM Agreement, the Company was permitted to sell from time to time through the Agents shares of the Company’s common stock with an aggregate sales price of up to $13 million. The Company agreed to pay a commission to the Agents of 3.0% of the gross proceeds of the sale of the shares sold under the Agreement and to reimburse the Agents for certain expenses. The Company also provided the Agents with customary indemnification rights. In June 2019, the Company canceled the ATM Agreement. The Company did not sell any shares under this ATM Agreement in 2019.

Subsequent to canceling the ATM Agreement with Roth and National, the Company entered into an At Market Issuance Sales Agreement (the “Opco Agreement”) with Oppenheimer & Co. Inc. (the “Agent”) on July 23, 2019. Pursuant to

the terms of the Opco Agreement, the Company may sell from time to time through the Agent shares of the Company's common stock, with an aggregate sales price of up to $15 million (the "Shares"). Any sales of Shares pursuant to the Opco Agreement will be made under the Company's effective "shelf" registration statement (the "Registration Statement") on Form S-3 (File No. 333-219434), which became effective on August 21, 2017 and the related prospectus supplement and the accompanying prospectus, as filed with the Securities and Exchange Commission (the "SEC"). Under the Opco Agreement, the Company may sell Shares through the Agent by any method that is deemed an "at the market offering" as defined in Rule 415 under the Securities Act of 1933, as amended. Sales of the Shares, if any, may be made at market prices prevailing at the time of sale, subject to such other terms as may be agreed upon at the time of sale, including a minimum sales price that may be stipulated by the Company's Board of Directors or a duly authorized committee thereof. The Company or the Agent, under certain circumstances and upon notice to the other, may suspend the offering of the Shares under the Agreement. The offering of the Shares pursuant to the Agreement will terminate upon the sale of Shares in an aggregate offering amount equal to $15 million, or sooner if either the Company or the Agent terminate the Agreement pursuant to its terms. The Company will pay a commission to the Agent of 3.0% of the gross proceeds of the sale of the Shares sold under the Agreement and reimburse the Agent for certain expenses. The Company has also provided the Agent with customary indemnification rights. The Company has not sold any shares under the Opco Agreement.

Adoption of 2015 Stock Plan

In 2015, the Board of Directors of the Company approved the Company's 2015 Stock Plan, which was amended in 2017 and 2018. The expiration date of the plan is December 5, 2025 and the total number of underlying shares of the Company's common stock available for grant to employees, directors and consultants under the plan is currently 4,500,000 shares. The awards under the 2015 Stock Plan can be in the form of stock options, stock awards, stock unit awards or stock appreciation rights.

The following table summarizes stock option activity for the nine months ended September 30, 2019:

	Stock Options Outstanding	Weighted Average Grant Date Fair Value	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2018	2,794,000	$ 1.78	$ 2.61	9.43	$ 21,200
Granted	1,115,000	$ 1.04	$ 1.30		
Exercised	(25,000)	$ 0.13	$ 0.20		
Forfeited	(103,000)	$ 1.29	$ 1.82		
Outstanding, September 30, 2019	3,781,000	$ 1.60	$ 2.28	8.61	$ 900
Exercisable, September 30, 2019	993,083	$ 2.28	$ 3.42	7.79	$ —

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

	Nine Months Ended September 30,			
	2019		2018	
Risk-free interest rate	1.04 % to	1.30 %	0.95 % to	2.24 %
Volatility	85 % to	100 %	70 % to	89 %
Expected life (years)	5.31 to	6.25	5 to	6.25
Expected dividend yield	—%		—%	

Stock-based compensation for the three and nine months ended September 30, 2019 and 2018, are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
General and administrative	$ 430	$ 207	$ 1,003	$ 709
Research and development	59	37	152	116
Total	$ 489	$ 244	$ 1,155	$ 825

During the nine months ended September 30, 2019, 1,115,000 stock options were granted. Options granted during 2019 have an aggregated fair value of $1.2 million which was calculated using the Black-Scholes option-pricing model. As of September 30, 2019, total compensation cost not yet recognized was $3.2 million and the weighted average period over which this amount is expected to be recognized is 2.51 years. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the above paragraph and table. The expected term of the options was computed using the "plain vanilla" method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin 107 because the Company does not have sufficient data regarding employee exercise behavior to estimate the expected term. The volatility was determined by referring to the average historical volatility of a peer group of public companies combined with the Company's due to the lack of sufficient historical data of its stock price. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

During the nine months ended September 30, 2019, the Company granted 316,907 restricted stock units, which vest annually in four equal installments. The weighted average grant date fair value was $1.31 per unit. As of September 30, 2019, total compensation cost not yet recognized was $0.4 million and the weighted average period over which this amount is expected to be recognized is 3.8 years. No restricted stock units were vested as of September 30, 2019 and no units were granted prior to 2019.

Consulting Agreement

In 2017, the Company entered into a consulting agreement for its investor relations operations. The consulting agreement initially covered a period of twelve months from the commencement date of July 29, 2017 and was extended in April 2018 until March 31, 2019. Pursuant to the original consulting agreement, in exchange for the consulting services, the Company issued two warrants (collectively, the "Warrants") to purchase 100,000 and 50,000 shares of common stock at exercise prices of $2.41 and $3.00 per share. Each of the Warrants vested over a 12-month period in equal monthly installments starting July 29, 2017, provided that the consultant was providing services to the Company pursuant to the consulting agreement on each vesting date. The Warrants became initially exercisable on August 8, 2017 and expire five years from the initial exercise date. In connection with the first extension of the consulting agreement, the Company issued the consultant a 3-year warrant to purchase 100,000 shares of common stock at an exercise price of $3.00 per share vesting in four quarterly installments. In addition, the Company paid $20,000 to the consultant per quarter pursuant to the first amendment to the consulting agreement. On July 8, 2019, the Company amended the existing consulting agreement for additional cash payments, with a right to cease cash payments by issuing the consultant a fully vested three-year warrant to purchase 150,000 shares of Company common stock, subject to NASDAQ listing of additional shares approval. On August 8, 2019, the Company elected to issue such warrant with an exercise price of $1.64. The Company recorded stock compensation expense for the non-employee consulting agreement of $0.1 million and $0.04 million for the three months ended September 30, 2019 and 2018, respectively, and $0.1 million for both the nine months ended September 30, 2019 and 2018.

$9 million Registered Direct Offering

In February 2018, the Company entered into a Securities Purchase Agreement with certain institutional investors for the sale of 4,290,000 shares of common stock, at a purchase price of $2.10 per share. Concurrently with the sale of the common stock, pursuant to the Purchase Agreement, the Company also sold warrants to purchase 2,145,000 shares of common stock. The Company sold the common stock and warrants for aggregate gross proceeds of approximately $9.0 million. The net proceeds from the transactions was approximately $8.2 million after deducting certain fees due to the placement agent and transaction expenses. Subject to certain beneficial ownership limitations, the warrants became exercisable on the six-month anniversary of the issuance date at an exercise price equal to $2.80 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the Purchase Agreement occurred on February 21, 2018.

$2.3 million Registered Direct Offering

In June 2018, the Company entered into a definitive agreement with institutional investors for a registered direct offering of securities with gross proceeds of approximately $2.3 million. In connection with the offering, the Company issued 1,092,636 registered shares of common stock at a purchase price of $2.105 per share. Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from the Company an unregistered warrant to purchase 0.65 of a share of common stock. The warrants have an exercise price of $2.02 per share, became exercisable six months from the date of issuance, and will expire five years from the initial exercise date. Roth Capital Partners LLC served as sole placement agent for the offering.

$5.25 million Registered Direct Offering

In March 2019, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Oppenheimer & Co. Inc. (the "Underwriter") relating to an underwritten offering (the "Offering") of 5,250,000 units (each a "Unit"), each unit consisting of (i) one share of the Company's common stock, and (ii) 0.5 of a warrant to purchase one share of common stock (each a "Warrant"). The public offering price of the Units was $1.00 per Unit, and the Underwriter agreed to purchase the Units from the Company pursuant to the Underwriting Agreement at a price of $0.93 per Unit. The Warrants included in the Units are immediately exercisable at a price of $1.10 per share, subject to adjustments in certain circumstances, and will expire five years from the date of issuance. The net proceeds from the transaction was approximately $4.7 million after deducting the underwriting discount and estimated offering expenses payable by the Company.

$15 million Registered Direct Offering

In April 2019, the Company entered into subscription agreements (each a "Subscription Agreement") with certain institutional investors (the "Investors") for the sale by the Company of 9,375,000 units (each a "Unit"), each Unit consisting of (i) one share of the Company's common stock, and (ii) 0.5 of a warrant to purchase one share of common stock (each a "Warrant"). The public offering price of the Units was $1.60 per Unit. The Warrants included in the Units are immediately exercisable at a price of $1.75 per share and will expire five years from the date of issuance. The net proceeds from the transaction was approximately $13.7 million after deducting the placement agent fees and estimated offering expenses payable by the Company.

Initial Public Offering Warrants

In connection with the Company's initial public offering completed in May 2016, the Company issued its underwriter a five-year warrant to purchase 107,802 shares of common stock at an exercise price of $7.50 per share.

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 2019 as a result of the losses recorded during the three and nine months ended September 30, 2019 and the additional losses expected for the remainder of 2019 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, 2019, the Company maintained a full valuation allowance for all deferred tax assets.

The Company recorded an income tax benefit for the three and nine months ended September 30, 2019 of $0.2 million resulting in a quarterly effective tax rate of 5.2% and an annual effective rate of 1.4%. The total income tax benefit is comprised of research and development tax credits recoverable, associated with Moleculin Australia Pty Ltd., (MAPL), a wholly owned subsidiary formed in June 2018, related to preclinical development in Australia for WP1732, an analog of WP1066. Aside from the Australia tax credit, the Company has recorded no income taxes for the three and nine months ended September 30, 2019 and 2018. 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 elsewhere in these notes, see below for a discussion of our commitments and contingencies as of September 30, 2019.

Lease Obligations Payable

Effective January 1, 2019, the Company adopted ASC 842, which requires recognition of a right-of use asset and a lease liability for all leases at the commencement date based on the present value of the lease payment over the lease term. In March 2018, the Company entered into a Lease Agreement (the “Lease”) which it uses for its corporate office space and headquarters. The term of the Lease began in August 2018 and will continue for an initial term of 66 months, which may be renewed for an additional 5 years. The Company is required to remit base monthly rent which will increase at an average approximate rate of 3% each year. The Company is also required to pay additional rent in the form of its pro-rata share of certain specified operating expenses of the Landlord. The leased space is located in Houston, Texas. The corporate office lease is classified as an operating lease.

In August 2019, the Company entered into an Amended Lease Agreement (the "Lab Lease") which it uses for lab space. The term of the Lease began in September 2019 and will continue for an initial term of 35 months, with no further right or option to renew. The Company is required to remit base monthly rent which will increase at an average approximate rate of 3% each year. The Lab Lease is classified as an operating lease. In August 2019, the Company entered into a sublease with Houston Pharmaceuticals, Inc. ("HPI"). The Company has granted HPI access to all of its Lab Lease space and HPI has agreed to pay the Company 50% of the Company's rent payable under the Lab Lease less 50% of any benefits from any sublease or other lab service agreement the Company may receive from its Lab Lease. Although HPI has access to the Company's Lab Lease space, it is the intent of the parties that they equally share the Lab Lease space for research purposes. The Company recorded approximately $3,400 in sublease income from the related party for the three and nine months ended September 30, 2019, respectively. Sublease income is recorded as other income on the Company's condensed consolidated statement of operations and comprehensive loss.

The Company recorded lease costs of $0.02 million and $0.03 million for the three and nine months ended September 30, 2019, respectively. The Company made an accounting policy election not to apply the recognition requirements to short-term leases. The Company recognizes the lease payments for short-term leases in profit or loss on a straight-line basis over the lease term, and variable lease payments in the period in which the obligation for those payments is incurred. The Company recorded total expenses for its short-term leases of $0.01 million and $0.04 million for the three and nine months ended September 30, 2019, respectively. The Company recorded lease costs for variable lease payments of $0.01 million and $0.02 million for the three and nine months ended September 30, 2019, respectively.

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

	Three Months Ended September 30,	Nine Months Ended September 30,
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ 20	$ 41
Right-of-use assets obtained in exchange for lease liabilities		
Operating leases	$ 212	$ 321

The minimum lease payments are expected to be as follows (in thousands):

Years Ending December 31,	Minimum Lease Payments
2019 (remaining three months)	$ 33
2020	135
2021	138
2022	105
2023	57
Thereafter	10
Total lease payments	478
Less: imputed interest	(74)
Present value of operating lease liabilities	$ 404

Under the prior lease guidance, future minimum lease payments at December 31, 2018 under long-term leases for the five years ending December 31, 2019 through 2023 and thereafter are as follows (in thousands): $48, $53, $54, $55, $56, and $5, respectively.

As of September 30, 2019, the weighted average remaining lease term is4.42 and 2.84 for the Lease and Lab Lease, respectively, and the weighted average discount rate is 9.6%. The interest rate implicit in lease contracts is typically not readily determinable and as such, the Company uses an incremental borrowing rate based on a peer analysis using information available at the commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment. During the nine months ended September 30, 2019, in addition to the initial adoption of the lease standard, the Company amended its Lab Lease which required additional right of use assets and liabilities to be recorded.

MD Anderson

Under agreements associated with Annamycin, the WP1122 Portfolio, and the WP1066 Portfolio, which includes WP1732, all described below, the Company is responsible for certain license, milestone and royalty payments over the course of the agreements. Annual license fees can cost as high as $0.1 million depending upon the anniversary. Milestone payments for the commencement of phase II and phase III clinical trials can cost as high as $0.5 million. Other milestone payments for submission of an NDA to the FDA and receipt of first marketing approval for sale of a license product can be as high as $ 0.6 million. Royalty payments can range in the single digits as a percent of net sales on drug products or flat fees as high as $0.6 million, depending upon certain terms and conditions. Not all of these payments are applicable to every drug. Total expenses under these agreements were $0.1 million and $0.1 million for the three months ended September 30, 2019 and 2018, respectively, and $0.2 million and $0.2 million during the nine months ended September 30, 2019 and 2018, respectively. On June 29, 2017, the Company entered into an agreement with MD Anderson licensing certain technology related to the method of preparing Liposomal Annamycin.

WP1122 Portfolio

The rights and obligations to an April 2012 Patent and Technology License Agreement entered into by and between IntertechBio and MD Anderson (the “IntertechBio Agreement”) have been assigned to MBI. Therefore, MBI has obtained a

royalty-bearing, worldwide, exclusive license to intellectual property, including patent rights, related to our WP1122 Portfolio and to our drug product candidate, WP1122.

WP1066 Portfolio

The rights and obligations to a June 2010 Patent and Technology License Agreement entered into by and between Moleculin LLC and MD Anderson (the "Moleculin Agreement") have been assigned to MBI. Therefore, MBI has obtained a royalty-bearing, worldwide, exclusive license to intellectual property rights, including patent rights, related to our WP1066 drug product candidate. In consideration, MBI must make payments to MD Anderson including an up-front payment, milestone payments and minimum annual royalty payments for sales of products developed under the license agreement. Annual Maintenance fee payments will no longer be due upon marketing approval in any country of a licensed product. One-time milestone payments are due upon commencement of the first Phase III study for a licensed product within the United States, Europe, China or Japan; upon submission of the first NDA for a licensed product in the United States; and upon receipt of the first marketing approval for sale of a licensed product in the United States. The rights the Company has obtained pursuant to the assignment of the Moleculin Agreement are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the U.S. government.

MBI entered into an out-licensing agreement with Houston Pharmaceuticals, Inc. ("HPI"), pursuant to which it granted certain intellectual property rights to HPI, including rights covering the potential drug candidate, WP1066 ("HPI Out-Licensing Agreement"). Under the HPI Out-Licensing Agreement the Company was required to make quarterly sponsored research payments totaling $0.75 million for the first twelve quarters following the effective date, of the HPI Out-Licensing Agreement, or May 2, 2016, in consideration for the right to development data related to the development of licensed products. Notwithstanding the Company's obligation to make the foregoing payments, the HPI Out-Licensing Agreement did not obligate HPI to conduct any research or to meet any milestones. Upon payment in the amount of $1.0 million to HPI within three years of the effective date of the HPI Out-Licensing Agreement ("HPI Option Repurchase Payment") MBI regained all rights to the licensed subject matter and rights to any and all development data and any regulatory submissions including any IND, NDA or ANDA related to the licensed subject matter and can end the license without any other obligation other than the aforementioned quarterly sponsored research payments. The option repurchase payment was paid on April 30, 2019 for $1.0 million and, accordingly, the HPI Out-Licensing Agreement was terminated. The $ 1.0 million payment was accrued and expensed under "Research and development" in the second quarter of 2018. Total expenses related to HPI were $ 0.0 million and $0.1 million for the three months ended September 30, 2019 and 2018, respectively, and $0.1 million and $1.2 million for the nine months ended September 30, 2019 and 2018, respectively.

In February 2018, MBI entered into a license agreement with MD Anderson covering a new group of molecules recently discovered in connection with research it has been sponsoring there called WP1732, a part of the WP1066 Portfolio.

Sponsored Research Agreements with MD Anderson

In January 2017, MBI amended its Sponsored Laboratory Study Agreement with MD Anderson where it was extended to the end of October 2018. In December 2017, MBI extended this Agreement until the end of October 2019 for total payment amount of $0.3 million spread over that period of time. In September 2018, the Company extended this Agreement until the end of October 2020 for total payment amount of $0.4 million spread over that period of time. In June 2019, the Company amended the Agreement to support the continuation of the project for total payment amount of $0.4 million. In October 2019, the Company amended the agreement until the end of October 2021 for a total additional payment amount of $0.4 million. The expenses recognized under the MD Anderson agreement with regards to the Sponsored Laboratory Study were $0.2 million and $0.1 million for the three months ended September 30, 2019 and 2018, respectively, and $0.4 million and $0.3 million, for the nine months ended September 30, 2019 and 2018, respectively.

Other Licenses

Dermin

In 2015, the Company obtained the rights and obligations for certain patent and technology development and license agreements with Dermin sp. z o.o. ("Dermin"). In connection with such agreements, certain intellectual property rights related to Annamycin, our WP1122 portfolio, and the Company's WP1066 portfolio were licensed to Dermin and Dermin was granted a royalty-bearing, exclusive license to manufacture, have manufactured, use, import, offer to sell and/or sell products in the field of human therapeutics under the licensed intellectual property. With respect to Annamycin, the license is limited to the

countries of Poland, Ukraine, Czech Republic, Hungary, Romania, Slovakia, Belarus, Lithuania, Latvia, Estonia, Netherlands, Turkey, Belgium, Switzerland, Austria, Sweden, Greece, Portugal, Norway, Denmark, Ireland, Finland, Luxembourg, Iceland, Kazakhstan, Russian Federation, Uzbekistan, Georgia, Armenia, Azerbaijan and Germany; provided that the Company has the right to remove Germany from the list of covered territories with a $0.5 million payment. With respect to WP1122, the license is limited to the countries of Belarus, Russia, Kazakhstan, Uzbekistan, Turkmenistan, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Ukraine. With respect to WP1066, the license is limited to the countries of Belarus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Ukraine. In each case, Dermin agreed to pay a royalty for the sale of any licensed product in the licensed territories and agreed to pay all out-of-pocket expenses incurred in filing, prosecuting and maintaining the licensed patents for which the license has been granted in the licensed territories. Dermin also agreed to provide a percentage of certain consideration that Dermin receives pursuant to sublicense agreements. In July 2019, Dermin assigned its rights under the foregoing license agreements to an affiliated entity, Exploration Invest Pte Ltd. ("Exploration"). On July 30, 2019, the Company and Exploration entered into a License Modification Agreement pursuant to which the Company agreed to issue Exploration shares of Company common stock valued at $0.5 million (based on the greater of the closing price of the common stock on the date of the agreement or the 10-day average closing price prior to the date of the agreement) in exchange for the modifying the license agreements to: (i) limit the licensed territory solely to Poland; and (ii) limit the patent rights and technology rights licensed to Exploration to the patent rights and technology rights that existed on the date the original license agreements were entered into with Dermin. On August 8, 2019, the Company issued 429,978 shares of Company common stock to Exploration to satisfy this commitment.

WPD Pharmaceuticals

On February 19, 2019, the Company sublicensed certain intellectual property rights, including rights to Annamycin, its WP1122 portfolio, and its WP1066 portfolio to WPD Pharmaceuticals sp. z o.o. ("WPD") (the "WPD Agreement"). WPD is affiliated with Dr. Waldemar Priebe, one of the Company's founders and largest shareholder. Under the WPD Agreement, the Company granted WPD a royalty-bearing, exclusive license to research, develop, manufacture, have manufactured, use, import, offer to sell and/or sell products in the field of human therapeutics under the licensed intellectual property in the countries of Germany, Poland, Estonia, Latvia, Lithuania, Belarus, Ukraine, Moldova, Romania, Armenia, Azerbaijan, Georgia, Slovakia, Czech Republic, Hungary, Uzbekistan, Kazakhstan, Greece, Austria, Russia, Netherlands, Turkey, Belgium, Switzerland, Sweden, Portugal, Norway, Denmark, Ireland, Finland, Luxembourg, Iceland ("licensed territories"), provided that the Company has the right to buyback Germany from the licensed territories by making a payment $0.5 million. On July 30, 2019, the Company entered into the aforementioned July 30, 2019 agreement with Dermin that satisfied the foregoing buyback right, and as such, Germany is no longer considered part of the licensed territories.

In consideration for entering into the WPD Agreement, WPD agreed that it must use Commercially Reasonable Development Efforts to develop and commercialize products in the licensed territories. For purposes of the WPD Agreement, the term "Commercially Reasonable Development Efforts" means the expenditure by or on behalf of WPD or any of its affiliates of at least: (i) $2.0 million during the first two years of the agreement on the research, development and commercialization of products in the licensed territories; and (ii) $1.0 million annually for the two years thereafter on the research and development of products in the licensed territories. This license is subject to the terms in the prior agreements entered into by the Company with Dermin and MDA.

WPD is actively seeking Polish government grants for research involving licensed drug candidates.

Prior to approval of the WPD Agreement, the Company's board of directors received a fairness opinion from Roth Capital Partners, LLC that stated that it was their opinion that the consideration the Company will receive from WPD pursuant to the WPD Agreement is fair, from a financial point of view, to the Company.

Animal Life Sciences

On February 19, 2019, the Company sublicensed certain intellectual property rights, including rights to Annamycin, its WP1122 portfolio, and its WP1066 portfolio in the field of non-human animals to ALI (the "ALI Agreement"). ALI is affiliated with Dr. Waldemar Priebe, one of its founders and its largest shareholder. Under the ALI Agreement, the Company granted ALI a worldwide royalty-bearing, exclusive license to research, develop, manufacture, have manufactured, use, import, offer to sell and/or sell products in the field of non-human animals under the licensed intellectual property. This license is subject to the terms in the prior agreements entered into by the Company and MDA. Under the ALI Agreement, the Company has the right to name an observer to ALI's board of directors. On August 8, 2019, the Company named its Chairman and CEO Walter V. Klemp to that position.

Since ALI and WPD are beginning the process to develop and commercialize products using the sublicensed intellectual property rights, the Company is currently unable to predict whether ALI and WPD will be successful in developing such products or when the Company may recognize royalty revenues related to such products.

Employment Agreements

The Company has agreements with certain employees to provide certain benefits in the event of termination where the base salary and certain other benefits would aggregate approximately $0.9 million using the rate of compensation in effect at September 30, 2019.

8. Subsequent Events

In addition to the subsequent events discussed elsewhere in these notes, no other events occurred.

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

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

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

Overview

Moleculin Biotech, Inc., a Delaware corporation, is a clinical stage pharmaceutical company focused on the treatment of highly resistant cancers. We have three core technologies, all of which are based on discoveries made at M.D. Anderson Cancer Center ("MD Anderson"). We have three drugs in four clinical trials in the US and Poland. Our clinical stage drugs are Annamycin, believed by management to be a "Next Generation" Anthracycline, being studied in the US and Poland for the treatment of relapsed or refractory acute myeloid leukemia, or AML, and WP1066, an Immune/Transcription Modulator targeting brain tumors, pancreatic cancer and AML. Additionally, a third drug, WP1220 (a molecule similar to WP1066), was approved for a clinical trial in January 2019 in Poland for the topical treatment of cutaneous T-cell lymphoma and for which patient treatments have begun, and the trial has achieved full enrollment. We are also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as Metabolism/Glycosylation Inhibitors.

We believe that our Next Generation Anthracycline, Annamycin, is unlike currently approved anthracyclines, as it is designed to avoid multidrug resistance mechanisms and has little to no cardiotoxicity (two problems common to all currently approved anthracyclines) — hence the use of the term "Next Generation." Annamycin is currently in two Phase I/II clinical trials and preliminary clinical data suggest it may have the potential to become the first successful therapy suitable for the majority of relapsed or refractory AML patients.

WP1066 is one of several STAT3 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, c-Myc and HIF-1α. These transcription factors are widely sought targets that may also play a role in the lack of efficacy of immune checkpoint inhibitors in certain resistant tumors.

We are also developing new compounds designed to exploit the potential uses of inhibitors of glycolysis such as 2-deoxy-D-glucose ("2-DG"), which we believe may provide an opportunity to cut off the fuel supply of tumors by taking advantage of their high level of dependence on glucose in comparison to healthy cells. A key drawback to 2-DG is its lack of drug-like properties, including a short circulation time and poor tissue/organ distribution characteristics. Our lead Metabolism/Glycosylation Inhibitor, WP1122, is a prodrug of 2-DG that appears to improve the drug-like properties of 2-DG by increasing its circulation time and improving tissue/organ distribution. New research also points to the potential for 2-DG to be capable of enhancing the usefulness of checkpoint inhibitors. Considering that 2-DG lacks sufficient drug-like properties to be practical in a clinical setting, we believe WP1122 may also become an important drug to potentiate checkpoint inhibitors.

Mission and Strategy

Moleculin is focused on developing treatments for highly resistant cancers. These include AML, glioblastoma, cutaneous t-cell lymphoma, pancreatic cancer, and others. Our diverse pipeline of technologies was built around the recognition that many highly resistant tumors tend to have a common set of traits, including an increase in multidrug resistant mechanisms, an evasion of the natural immune system, a marked upregulation of certain key oncogenic transcription factors and an increased dependence on glycolysis for energy production. We believe each of these elements may be addressed by the unique and innovative mechanisms introduced by one or more of our three core technologies.

We believe this approach not only provides the opportunity to help the many patients in need of alternative therapies, but also to work in combination with numerous existing technologies that often fail as tumors present immediate or acquired resistance. We believe showing even modest improvements in highly resistant cancers may lead to accelerated approval pathways, potentially reducing the time and capital required to ultimately realize success.

Corporate Overview

We were founded in 2015 in order to combine and consolidate the development efforts involving several oncology technologies, based on license agreements with MD Anderson. This effort began with the acquisition of the Annamycin development project from AnnaMed, Inc., or AnnaMed, followed by the acquisition of the license rights to the WP1122 Portfolio from IntertechBio Corporation, or IntertechBio. Further, on behalf of Moleculin, LLC, we entered into a co-development agreement with Houston Pharmaceuticals, Inc., or HPI, which culminated with the merger of Moleculin, LLC into MBI coincident with our initial public offering allowing us to gain control of the WP1066 Portfolio.

Moleculin, LLC was formed in 2006 and was working to develop the WP1066 Portfolio it licensed from MD Anderson. On May 2, 2016, Moleculin, LLC was merged with and into MBI. As a result of the merger, we issued the holders of Moleculin, LLC equity interests and convertible notes representing in the aggregate 999,931 shares of our common stock. Since Moleculin, LLC commenced operations in 2006, substantially all of its efforts had been focused on research, development and the advancement of the WP1066 Portfolio. Moleculin, LLC did not generate any revenue from product sales and, as a result, incurred significant losses.

In June 2018, we formed Moleculin Australia Pty. Ltd., a wholly owned subsidiary to oversee pre-clinical development in Australia. The Australian government provides an aggressive incentive for research and development carried out in their country. We believe having an Australian subsidiary could provide an opportunity to speed up pre-clinical development and reduce the overall cost of our continued drug development efforts.

We do not have manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, we do not have a sales organization.

Technology Overview

We have been granted royalty-bearing, worldwide, exclusive licenses for the patent and technology rights related to all of our drug technologies, as these patent rights are owned by MD Anderson. The Annamycin drug substance is no longer covered by any existing patent protection, but on July 10, 2019, we submitted patent applications for formulation, synthetic process and reconstitution related to our Annamycin drug product candidate. If these patent applications are approved, of which we can provide no assurance, this would provide potentially 20 years of protection for our drug. Independently from potential patent protection, in 2018 we have received Orphan Drug designation ("ODD") from the FDA for Annamycin for the treatment

of AML and, in 2019 we received ODD for WP1066 for the treatment of glioblastoma. This may enable market exclusivity of 7 years from the date of approval of a New Drug Application (“NDA”) in the United States. During that period, the FDA generally could not approve another product containing the same drug for the designated indication. We also intend to apply for similar status in the European Union (“EU”) where market exclusivity extends to 10 years from the date of Marketing Authorization Application (“MAA”). Separately, the FDA may also grant market exclusivity of 5 years for newly approved new chemical entities (of which Annamycin would be one), which would preclude approval of any other annamycin product, but there can be no assurance that such exclusivity will be granted. Furthermore, in April 2019, the FDA approved the Company's request for Fast Track Designation for Annamycin for the treatment of relapsed or refractory AML. Fast Track Designation, the purpose of which is to expedite drug development and approval, is granted to drugs intended to treat serious conditions and where data demonstrate the potential to address an unmet medical need.

Next Generation Anthracycline

Chemotherapy continues to be a cornerstone of cancer therapy. Despite the progress made with immunotherapy and precision medicine, the first-line treatment for many cancers continues to include chemotherapy. And, in part because of the emphasis placed on alternatives to chemotherapy, we believe that not enough has been done to improve chemotherapeutic agents to make them safer and more effective. Anthracyclines are a class of chemotherapy drugs designed to destroy the DNA of targeted cancer cells. Acute leukemia is one of a number of cancers that are usually treated with anthracyclines. In the case of acute leukemia, anthracyclines are typically used in “induction therapy,” where the goal is to induce sufficient remission of patients’ blood-born tumor cells to allow for a curative bone marrow transplant.

Two key factors limit the safety and effectiveness of anthracyclines: cardiotoxicity (potential to damage the heart) and multidrug resistance. We believe Annamycin may overcome these two factors; if preliminary data are borne out, Annamycin may ultimately provide clinically meaningful benefits over currently approved anthracyclines in treating certain cancers. Preliminary data from very early-stage clinical trials suggest acute leukemia as a potentially opportune indication in which to further study Annamycin.

One of the key dose-limiting toxicities associated with currently available anthracyclines (including the anthracycline in the approved drug, Vyxeos) is the propensity to induce life-threatening heart damage (also known as cardiotoxity). This is a particularly significant risk for pediatric leukemia patients, whose life spans can be severely shortened by the induction therapy intended to cure them of acute leukemia. In the animal model recommended by the FDA as an indicator of human cardiotoxicity, the non-liposomal (free) form of Annamycin has been shown to be significantly less likely than doxorubicin to create heart lesions in mice, and the liposomal formulation ("L-Annamycin") has been shown in these same models to have reduced cardiotoxicity to the point where it is unlikely to cause harm to human patients. If this characteristic is shown to be the same in humans, it may allow L-Annamycin to be used more aggressively to help patients achieve remission. This would be especially valuable in the case of pediatric acute leukemia (both AML and ALL) because of the potential impact of cardiotoxicity on long-term survival. In our current Phase I/II trial for Annamycin, we are collecting data to further validate the design intent of Annamycin to have little or no cardiotoxicity. Unless otherwise noted, all of our references to Annamycin refer to the liposomal form or L-Annamycin.

In addition, the effectiveness of currently approved anthracyclines is limited by their propensity for succumbing to “multidrug resistance.” This can occur where, as a natural defense mechanism, transmembrane proteins acting as transporters (one type of which is referred to as a “P-glycoprotein pump” or “ABCB1 transporter”) develop on the outer surface of cells to expel perceived threats like anthracyclines. In many instances, the likelihood of cardiotoxicity (and other serious side effects) prevents increasing the dosing of current therapies in order to overcome multidrug resistance. As a result, most patients cannot receive current anthracyclines in doses that are adequate to produce lasting remission and thereby qualify for a bone marrow transplant. A laboratory study has suggested that Annamycin may resist being expelled by P-glycoprotein pumps and similar multidrug resistance transporters, which may mean the drug circumvents multidrug resistance. This characteristic has been shown in pre-clinical testing to allow for higher drug uptake in diseased cells, which we believe could allow for more effective induction therapy with less risk to the patient.

Additionally, preclinical research in animal models at MD Anderson demonstrated that Annamycin is able to significantly improve survival in an aggressive form of triple negative breast cancer metastasized to the lungs in animal models. Coupled with research demonstrating that Annamycin is capable of accumulating in the lungs at very high levels, this suggests that Annamycin may be well suited to become a treatment for lung-localized tumors.

STAT3 Immune/Transcription Modulators: Enabling Immune Response and Inhibiting p-STAT3 and other Oncogenic Transcription Factors –

We believe our WP1066 Portfolio (including lead drugs WP1066, WP1220 and WP1732) represents a novel class of agents capable of hitting multiple targets, including the activated form of a key oncogenic transcription factor, STAT3. A substantial body of published research has identified STAT3 as a master regulator of a wide range of tumors and has linked the activated form, p-STAT3, with the survival and progression of these tumors. For this reason, it is widely believed that targeted inhibition of p-STAT3 may be an effective way to reduce or eliminate the progression of these diseases.

The high level of anticancer activity demonstrated in multiple tumors in animal models by WP1066 and WP1732 is potentially related to their ability to also inhibit such important key oncogenic transcription factors like c-Myc and HIF-1α. In addition to direct anticancer effects not related to the function of the immune system, our lead drug WP1066 has also been shown to boost immune response in animals, in part by inhibiting activity of Regulatory T cells ("Tregs"), which are coopted by tumors to evade the immune system. We believe the dual effect of (1) directly inhibiting tumor growth and inducing tumor cell death and (2) separately boosting and directing the natural immune response to tumors is therapeutically highly promising. If additional preclinical and clinical data validate the two avenues of apparent activity, this class of drugs may be well-suited to treat a wide range of tumors, both as single agents and as critical elements of successful combination therapies targeting even some of the most difficult-to-treat cancers.

The recent oncology drug landscape has been dominated by immunotherapy, specifically including checkpoint inhibitors. In just the last 5 years, checkpoint inhibitors (such as Opdivo and Keytruda) have reached over $10 billion in annual revenues. To summarize checkpoint blockade therapy, the T-Cells within an individual's own immune systems should be capable of identifying tumor cells and destroying them before they destroy the individual. Unfortunately, tumors develop the ability to prevent this natural immune response by regulating the expression of certain receptors referred to as "immune checkpoints" that then bind to T-Cells and prevent them from attacking the tumor. Immune checkpoint inhibitors are antibodies that block these receptor mechanisms and allow the T-Cells to act normally and attack the tumor.

In certain types of tumors, like melanoma, checkpoint inhibitors work well, and the results can be impressive, creating durable suppression of tumors where no other therapy had succeeded. However, despite the outstanding results in select patients, checkpoint inhibitors benefit only a limited number of patients in certain cancers, and they are essentially not effective in what are called "non-responsive" tumors like glioblastoma and pancreatic cancer, among others. As a result, companies are now focusing heavily on combination therapies, combining immune checkpoint inhibitors with chemotherapy, as well as other agents. We believe there is a clear need for new chemotherapeutic agents that, by their specific mechanism of action, would produce potent combination effects with immune checkpoint inhibitors, and that additionally can boost immune system response on their own. In this regard, there is early nonclinical evidence that WP1066, as a single agent, has the ability to reverse immune tolerance in brain tumor patients (Cancer Res, 67(20), 9630, 2007), and preliminary data in animal models that suggests WP1066 may have a potential for combination use with checkpoint inhibitors.

Recently published research papers have presented several findings that may point to major new opportunities for Moleculin's WP1066 class of drugs. One such article suggested that our STAT3 inhibitor WP1066 abrogated PD-L1/2 expression in cancer cells and may be a useful agent in addition to checkpoint inhibitor immunotherapy in cancer patients (J Clin Exp Hematop, 57(1), 21-25, 2017). Other published results show that CTLA4-induced immune suppression occurs primarily via an intrinsic STAT3 pathway, suggesting that, through its inhibition of activated STAT3, WP1066 might work well in combination with this checkpoint inhibitor (Cancer Res, 77(18), 5118–28, 2017).

A separate paper presents selected key transcription factors as being responsible for the upregulation of an often-targeted checkpoint actor in tumors known as PD-L1. Some of the most important transcription factors identified were HIF-1α, c-Myc and STAT3, the very targets for which WP1066 was designed (Front Pharmacol, 2018 May 22, 9:536, doi: 10.3389/ fphar.2018.00536, eCollection 2018). In summary, although much of the data is nonclinical and all of it is preliminary, we are optimistic that administration of WP1066 could lead to improved treatment results in many patients receiving checkpoint inhibitor therapy.

Metabolism/Glycosylation Inhibitors: Using the Warburg Effect to Starve Tumor Cells to Death –

Science has recognized that many types of cancer cells have a unique metabolism, distinct from that of normal cells. Cancer cells' dependence on glycolysis (a specific way of converting glucose into energy) to proliferate and metastasize has been described as the "sweet tooth of cancer" and is a classic example of how the metabolism of cancer cells and normal cells differ. Glycolysis is a glucose-intensive means of producing energy that is used by normal cells only if oxygen levels are low.

However, many types of tumor cells are essentially addicted to glycolysis even in the presence of abundant oxygen. This is known as the “Warburg Effect” after its discoverer, Dr. Otto Warburg, and such tumors are said to be highly “glycolytic.”

This phenomenon of tumors relying preferentially on glycolysis and the resulting dramatic increase of glucose uptake to fulfill their metabolic demands has already been utilized very effectively in cancer diagnostics. It is the Warburg Effect that enables imaging of actively growing tumors by positron emission tomography (“PET scans”). This diagnostic test uses a fluorine-18 radiolabeled glucose decoy called F18DG that accumulates disproportionately in tumors, using the same process that increases glucose uptake and retention in cancer cells.

The success of PET scanning points to the potential therapeutic benefit of the tumor-specific inhibition of glycolysis that would block energy (adenosine triphosphate (“ATP”)) production and could potentially “starve tumor cells to death” and/or make them sensitive to other existing therapies, including radiotherapy. Unsuccessful attempts to realize this therapeutic potential have been made in the past, using a glucose decoy known as “2-deoxy-D-glucose” ("2-DG"). Those attempts to target the metabolism of tumor cells have failed, we believe, because of 2-DG’s lack of drug-like properties that include rapid metabolism, short half-life and limited tissue-organ distribution. Essentially, not enough 2-DG could be delivered to its intended target.

We have designed and are studying a novel and patented prodrug of 2-DG (WP1122). We believe WP1122 has the potential for developing into a technology platform for enabling increased cellular uptake, increased drug half-life and, importantly, enabling greater uptake and retention in organs where the most resistant and glycolytic tumors are localized, including the brain and pancreas.

Altering Glycosylation to Enhance Immune Checkpoint Therapy –

A recently published study (Am J Cancer Res, 8(9), 1837-1846, 2018) focused on the analysis of tumor resistance to immune checkpoint therapy. The study found that a process known as glycosylation plays an important role in the ability of checkpoint receptors to suppress immune activity and thereby protect tumors from attack. The researchers discovered that an alteration of the glycosylation of these receptor mechanisms could effectively prevent this evasion of the immune system. This study found that 2-deoxyglucose, or 2-DG, was capable of making this alteration. Although the data are preliminary, the findings suggest that 2-DG could act as an effective anticancer agent in combination with checkpoint inhibitors and potentially with other anticancer therapies.

Attempting to use 2-DG as a drug, however, faces the same problems discussed above. 2-DG’s short circulation time and lack of other drug-like properties mean the drug does not stay in the system long enough or concentrate sufficiently in targeted organs, which severely limits its effectiveness. This suggests a possible role for our drug candidate, WP1122. WP1122 is a prodrug of 2-DG, meaning it is a molecule that may be able to be converted into pharmacologically active 2-DG within the body of the patient. The design of WP1122 is intended to allow for a longer circulation time and improved organ distribution, which should provide it a greater opportunity to become an effective drug.

We intend to study WP1122 for both its ability to directly inhibit tumor activity and to potentiate existing therapies via an inhibition of tumor metabolism and to improve the performance of checkpoint inhibitors by reducing the effect of glycosylation and have begun the necessary preclinical work required to file an IND.

Clinical Activity

Annamycin had previously been in clinical trials with a prior drug developer pursuant to an application for Investigational New Drug status (“IND”) that had been filed with the FDA. Due to a lack of development activity by the prior drug developer, this IND was terminated. To permit the renewed investigation of Annamycin, we submitted a new IND for a Phase I/II trial for the treatment of relapsed or refractory AML in August 2017, which was subsequently allowed by the FDA in September 2017. Patient treatment began in the US in March 2018. In March 2019, we announced that the first cohort in the US was completed and announced top-line results. We are now in the second cohort in our Phase I portion of the US trial.

With regard to additional Annamycin clinical activity, we received Polish National Office approval in June 2018 for a Clinical Trial authorization (“CTA”) in Poland, which enabled us to begin a Phase I/II clinical trial there to study Annamycin for the treatment of relapsed or refractory AML. During the first half of 2019, we began screening and treating patients in Poland. We have now completed the first two cohorts and are now treating patients in the third cohort.

We continue to recruit and contract with clinics both in the United States and Poland. We can provide no assurance of additional recruitment or that treatments will occur in the near term and on a timely basis, if at all.

With the additional preclinical research on Annamycin's impact on lung localized tumors, we expect to announce a related clinical trial in 2020. In October 2019, we announced the expansion of Annamycin production to supply the above-mentioned AML clinical trials, as they continue, and a trial for the treatment of lung localized tumors.

A physician-sponsored IND for a Phase I trial of WP1066 in patients with recurrent malignant glioma and brain metastasis from melanoma was allowed by the FDA in December 2017. In July 2018, this trial opened for recruitment in the US. This trial is now in its fourth cohort of the Phase I portion of the planned protocol. Because this trial is physician led, we are limited in our ability to manage the trial. We expect to transfer the IND for this trial from MD Anderson to Moleculin in 2020.

With regard to additional clinical activity on other drugs, we initiated a proof-of-concept clinical trial in Poland to study our drug candidate WP1220, a part of the WP1066 portfolio, for the topical treatment of cutaneous T-cell lymphoma ("CTCL"). In August 2019, we completed full enrollment in a proof-of-concept clinical trial in Poland to study WP1220, a part of the WP1066 portfolio, for the treatment of CTCL. Polish authorities approved our CTA for this use in January 2019, and the trial began enrolling patients in March 2019 In August 2019, we completed full enrollment in a proof-of-concept clinical trial in Poland to study WP1220, a part of the WP1066 portfolio, for the treatment of CTCL. Polish authorities approved our CTA for this use in January 2019, and the trial began enrolling patients in March 2019.

We have begun planning and performing the necessary pre-clinical work required to submit an IND or its foreign equivalent for WP1732 or another intravenous formulation of WP1066, as well as WP1122. We expect to submit these INDs in 2021. In June 2018, we entered into an agreement with The University of Iowa Pharmaceuticals for the development of a formulation for WP1732. This agreement marked the beginning of creating a preclinical package to submit to the FDA in order to request Investigational New Drug status. We have now completed initial formulation development, and our IND-enabling toxicology work will be progressing via our Australian subsidiary, Moleculin Australia. As a result of our preclinical work to date, we are investigating improvements to the formulation of WP1732. Furthermore, we are investigating additional methods of making WP1066 deliverable intravenously.

We also continue to sponsor ongoing research at MD Anderson in order to improve and expand our drug development pipeline.

Recent Business Developments

Below are recent business developments.

New Preclinical Data Further Suggests Anti-tumor Efficacy of Annamycin in Both Human and Murine AML models

On October 29, 2019, we announced the presentation of a poster at the AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference in Boston, MA. The poster, entitled "Dose and Schedule-Dependent Efficacy of Liposomal Annamycin in Pre-clinical Models of Acute Myeloid Leukemia," presents preclinical data documenting the high activity of Annamycin against AML, including in vitro studies in a panel of human AML cell lines, as well as in vivo studies in both human and murine AML models developed under the Company's sponsored research agreement with MD Anderson.

Comments from the FDA Regarding our US AML Trial with Annamycin

During September and October 2019, we received comments from the FDA related to the proposed, revised protocol of our US trial with Annamycin treating relapse and refractory AML patients. Management believes that it has implemented all changes suggested or requested by the FDA in a revised protocol submitted to the FDA. We do not anticipate any material impact on the timing of conducting the study. Details of this trial are available on www.clinical trials.gov (NCT03315039).

Increases Annamycin Production

On October 22, 2019, we announced the expansion of Annamycin production commitments in response to management's assessment of positive AML clinical trial activity and the potential expansion of indications for use to include lung-localized tumors. The purchase commitment arranged through Davos Pharmaceuticals includes moving final production of Annamycin to a larger-scale suite within BSP Pharmaceuticals S.p.A. ("BSP") in Latina, Italy. Until now, BSP has been producing the clinical supplies of Annamycin in a smaller pilot-scale suite. In connection with this work, we have also

contracted with BSP and the maker of the Annamycin active pharmaceutical ingredient (API) to develop methods for eventual commercial scale production.

Filing of Patent Protection for New Discovery

On September 16, 2019, we announced our sponsored research at MD Anderson Cancer Center has resulted in the filing of a new patent on behalf of MD Anderson Cancer Center covering the combination of our immune-stimulating/transcriptional-modulator, WP1066, with well-known immune checkpoint inhibitors.

CTRC Approval of WP1066 Pediatric Brain Tumor Trial

On August 20, 2019, we announced approval by the Emory University Clinical Trial Review Committee (CTRC) to move forward with an investigator initiated clinical trial of our immune-stimulating/transcriptional-modulator, WP1066, for the treatment of pediatric brain tumors. The trial will take place at the Aflac Cancer and Blood Disorders Center at Children's Healthcare of Atlanta.

Completion of Lymphoma Trial Enrollment

On August 13, 2019, we announced that we had reached full enrollment in our proof of concept clinical trial to evaluate our p-STAT3 inhibitor, WP1220, for the topical treatment of CTCL. If successful, this study could be an important first demonstration of a therapeutic effect in humans from such a p-STAT3 inhibitor. We believe showing activity with one of our STAT3 inhibitors could be an indicator of both the value of p-STAT3 as a target and the potential for our drugs in other cancers where STAT3 is highly activated.

WP1066 Potentially Capable of Immune Reprogramming in Glioblastoma Animal Models

On August 6, 2019, we announced that a paper entitled "Immunological Reprogramming in the CNS Tumor Microenvironment and Therapeutic Efficacy of Radiotherapy with STAT3 Blockade" would be presented at the Inaugural Conference on Brain Metastases, in New York City, August 16-17, 2019. Dr. Martina Ott, of MD Anderson Cancer Center, will be presented the findings of research she conducted in collaboration with Dr. Amy Heimberger (the Principle Investigator of the current investigator-initiated clinical trial of WP1066 for brain tumors) in combining WP1066 with radiation therapy in glioblastoma animal models. One of the findings of her research that is especially encouraging is that immune-competent mice treated with both radiation and WP1066 developed an immunological memory that enabled them to prevent regrowth of the tumor after these tumor cells were reintroduced. The result was the development of long-term survivors, leading to an increase in overall survival in these models. Of note was that mice with a compromised immune system did not show this effect. We believe that these findings may have a profound impact on understanding the role of STAT3 inhibition, and it will help focus our continued development of WP1066 in this disease. This study was also particularly interesting because it showed the most robust immunological responses were located in the CNS (Central Nervous System) tumor microenvironment rather than peripheral non-tumor tissue. Importantly, the study indicated that the combination of STAT3 inhibition with whole brain radiotherapy may have the capacity to enhance the therapeutic effect against established tumors based on immunological competence. There remains much work to be done to follow up on these data, of course. In that regard, we plan to explore this potential in human clinical trials.

At Market Issuance Sales Agreement

We entered into an At Market Issuance Sales Agreement with Oppenheimer & Co. Inc. on July 23, 2019 (the "Opco Agreement"). Pursuant to the terms of the Opco Agreement, we may sell from time to time through the Agent shares of our common stock with an aggregate sales price of up to $15 million. Any sales of shares pursuant to the Opco Agreement will be made under our effective “shelf” registration statement on Form S-3 (File No. 333-219434), which became effective on August 21, 2017 and the related prospectus supplement and the accompanying prospectus, as filed with the Securities and Exchange Commission. Under the Opco Agreement, we may sell shares through the Agent by any method that is deemed an “at the market offering” as defined in Rule 415 under the Securities Act of 1933, as amended. Sales of the shares, if any, may be made at market prices prevailing at the time of sale, subject to such other terms as may be agreed upon at the time of sale, including a minimum sales price that may be stipulated by our Board of Directors or a duly authorized committee thereof. We or the Agent, under certain circumstances and upon notice to the other, may suspend the offering of the shares under the Agreement. The offering of the shares pursuant to the Agreement will terminate upon the sale of shares in an aggregate offering amount equal to $15 million, or sooner if either we or the Agent terminate the Opco Agreement pursuant to its terms. We will pay a commission to the Agent of 3.0% of the gross proceeds of the sale of the shares sold under the Opco Agreement and reimburse the Agent for

certain expenses. We have also provided the Agent with customary indemnification rights. We have not sold any shares under the Opco Agreement.

Annamycin in Acute Myeloid Leukemia in Poland Advances to 3rd Cohort

On July 18, 2019, we announced additional interim safety and efficacy data from our ongoing open label, single arm Phase 1/2 study of Annamycin in Poland. Three patients were treated at a dose level of 150 mg/m^2 with no drug-related adverse events, including no signs of cardiotoxicity. The results for all three patients were reviewed by the Drug Safety Review Committee, which determined that the trial could progress to the next higher dose level of 180 mg/m^2. To date in Poland, one patient receiving the higher dose experienced grade 2 mucositis (which resolved to grade 1 within 2 days) and no other adverse events related to Annamycin have been reported. One patient has completed treatment in the 120 mg/m^2 (second) cohort in our parallel US clinical trial (the US trial started at a lower initial dose of 100 mg/m^2).

New Patents for Annamycin

On July 10, 2019, we announced we have filed new patents covering the production and reconstitution of Annamycin, which is currently in two clinical trials for the treatment of relapsed or refractory AML. If these patent applications are approved, which cannot be assured, it would potentially give us 20 years of protection for a finished drug product incorporating those characteristics.

Interim Results in First Cohort of Phase 1/2 Clinical Studies of Annamycin in Europe

On May 7, 2019, we announced additional interim safety and efficacy data from our ongoing open label, single arm Phase 1/2 study of Annamycin in Poland. After receiving a single starting dose of 120 mg/m2 in the first cohort of the dose escalation phase of the trial, 2 of 3 patients treated responded sufficiently to qualify for a potentially curative bone marrow transplant. The results for all 3 patients were reviewed by the Safety Review Committee, which determined that no drug-related adverse events were observed that would prevent advancing the trial to the next higher dose level of 150 mg/m2. To date in the European trial, one patient experienced grade 2 mucositis (which resolved to grade 1 within 2 days) and no other adverse events related to Annamycin have been reported. No signs of cardiotoxicity have been reported in either trial.

$15.0 Million Registered Direct Offering

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

FDA Approval of Fast Track Designation for Annamycin

On April 18, 2019, we announced that the FDA approved our request for Fast Track Designation for Annamycin for the treatment of AML.

Annamycin Found to be Active Against Metastatic Lung Cancer in Pre-Clinical Testing

On April 17, 2019, we announced that the ongoing sponsored research at the University of Texas MD Anderson Cancer Center has now demonstrated that Annamycin is able to significantly improve survival in an aggressive form of triple negative breast cancer metastasized to the lungs in animal models.

Agreement with Emory University to Conduct Pediatric Brain Tumor Trial

On April 11, 2019, we announced that we have entered into an agreement with Emory University to conduct a Phase 1 clinical trial of WP1066 in children with recurrent or refractory malignant brain tumors. The study will be conducted at the Aflac Cancer & Blood Disorders Center at Children's Healthcare of Atlanta.

Underwritten Public Offering

On March 29, 2019, we completed an underwritten public offering of an aggregate of 5,250,000 units at a public offering price of $1.00 per unit. Each unit is comprised of one share of common stock and 0.5 of a warrant to purchase one share of common stock for a total of 5,250,000 shares of common stock and warrants to purchase 2,625,000 shares of common stock. Each warrant has an exercise price of $1.10 per share and is exercisable immediately. The warrants will expire five years from the date of issuance. The gross proceeds of the offering were $5.25 million, prior to deducting the underwriting discount and other estimated offering expenses.

Positive Interim Results in First Cohort of Phase 1/2 Clinical Studies of Annamycin in Acute Myeloid Leukemia in the US and in Europe

On March 26, 2019, we announced positive interim safety and efficacy data from two ongoing open label, single arm Phase 1/2 studies of Annamycin. In the first study, being conducted in the US, four patients have completed treatment at 100 mg/m^2 with no significant adverse events related to Annamycin, and the study will now proceed to the next higher dose of 120 mg/m^2. No signs of cardiotoxicity have been reported in either trial.

First Patients Enrolled in Lymphoma Clinical Trial

On March 19, 2019, we announced that the first two patients have been enrolled in our European clinical trial of WP1220 for the topical treatment of CTCL.

Memorial Sloan Kettering Chief of Leukemia Joins Science Advisory Board

On March 18, 2019, we announced that Dr. Martin Tallman, Chief of Leukemia for Memorial Sloan Kettering Cancer Center joined the Company's Science Advisory Board.

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,	
	2019	2018	2019	2018
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	2,785	1,332	7,816	6,801
General and administrative	1,672	1,248	4,748	3,859
Depreciation and amortization	51	11	147	27
Total operating expenses	4,508	2,591	12,711	10,687
Loss from operations	(4,508)	(2,591)	(12,711)	(10,687)
Other income (expense):				
Gain from change in fair value of warrant liability	124	573	3,059	1,614
Other expense	5	(21)	5	(23)
Interest income, net	5	1	10	5
Net loss	$ (4,374)	$ (2,038)	$ (9,637)	$ (9,091)

Three Months Ended September 30, 2019 Compared to Three Months Ended September 30, 2018

Research and Development Expense. Research and development ("R&D") expense was $2.8 million and $1.3 million for the three months ended September 30, 2019 and 2018, respectively. The increase of $1.5 million is mainly related to increased clinical activity due to an increase in clinical trials (2 drugs in 3 clinical trials in 2018, versus 3 drugs in 4 clinical trials in 2019), as well as the issuance of common stock to Exploration Invest Pte Ltd for $0.5 million, related to the exercise of the option to reacquire certain license rights in Germany under the Dermin License Agreements.

General and Administrative Expense. General and administrative expense was $1.7 million and $1.2 million for the three months ended September 30, 2019 and 2018, respectively. The increase of $0.5 million was mainly attributable to increase in payroll costs for an additional finance and office staff and stock-based compensation expense for vested warrants issued to a consultant and annual employee stock options.

Gain from Change in Fair Value of Warrant Liability. We recorded a net gain of $0.1 million in the third quarter of 2019 as compared to a net gain of $0.6 million in the third quarter of 2018, 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 certain of the warrants at the time of each warrant exercise 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, 2019 Compared to Nine Months Ended September 30, 2018

Research and Development Expense. R&D expense was $7.8 million and $6.8 million for the nine months ended September 30, 2019 and 2018, respectively. The increase of $1.0 million is mainly related to increased clinical trial activity in 2019 as compared to 2018 (2 drugs in 3 clinical trials in 2018, versus 3 drugs in 4 clinical trials in 2019), as well as the issuance of common stock to Exploration Invest Pte Ltd for $0.5 million, as discussed above.

General and Administrative Expense. General and administrative expense was $4.7 million and $3.9 million for the nine months ended September 30, 2019 and 2018, respectively. The increase of $0.8 million was mainly attributable to increase

in payroll costs for an additional finance and office staff, stock-based compensation expense for vested warrants issued to a consultant and annual employee stock options.

Gain from Change in Fair Value of Warrant Liability. We recorded a net gain of $3.1 million in the nine months ended September 30, 2019, as compared to a net gain of $1.6 million in 2018, 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 certain of the warrants at the time of each warrant exercise 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,	
	2019	**2018**
Net cash used in operating activities	$ (12,521)	$ (9,093)
Net cash used in investing activities	(42)	(303)
Net cash provided by financing activities	20,854	10,284
Effect of exchange rate changes on cash and cash equivalents	(16)	(2)
Net increase in cash and cash equivalents	$ 8,275	$ 886

As of September 30, 2019, there was no cash on hand in Australia however there was a local tax receivable of $0.2 million which was collected in October 2019. We maintain a bank account in Australia and know of no related limitations impacting our liquidity there.

Cash used in operating activities

Cash used in operations was $12.5 million for the nine months ended September 30, 2019. This $3.4 million increase over the prior year of $9.1 million was mainly due to: 1) payments for developing, manufacturing and testing drug product as we prepared for clinical trials; 2) an increase in R&D employee and contractor headcount and associated payroll costs; 3) an increase in paid sponsored research and related expenses; and 4) an increase in license fees. These are all a reflection of the ongoing clinical and pre-clinical activity and the associated increase in G&A support for our three core drug technologies.

Cash used in investing activities

Net cash used in investing activities was $0.04 million for the nine months ended September 30, 2019 compared to $0.3 million for the nine months ended September 30, 2018. The decrease relates to purchases in 2018 related to furniture and fixtures and leasehold improvements on the new office location, as well as the installation of a new accounting system in 2018.

Cash provided in financing activities

In April 2019, we completed subscription agreements with institutional investors to purchase an aggregate of 9,375,000 units at a public offering price of $1.60 per unit in a registered direct offering. Each unit was comprised of one share of common stock and 0.5 of a warrant to purchase one share of common stock resulting in gross proceeds of $15.0 million. Each warrant has an exercise price of $1.75 per share and is exercisable immediately. The warrants will expire five years from the date of issuance.

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

In March 2019, we completed an underwritten offering of 5,250,000 units, each unit consisting of (i) one share of common stock and (ii) 0.5 of a warrant to purchase one share of common stock. The public offering price of the units was $1.00 per unit, and the underwriter agreed to purchase the units from us at a price of $0.93 per Unit. The warrants included in the units are immediately exercisable at a price of $1.10 per share, subject to adjustments in certain circumstances, and will expire

five years from the date of issuance. The net proceeds from the transaction was $4.7 million after deducting the underwriting discount and estimated offering expenses.

In June 2018, we entered into an agreement with institutional investors for a registered direct offering of securities for the sale of 1,092,636 shares of our common stock, at a purchase price of $2.105 per share. Concurrently with the sale of the common shares, we also sold warrants to purchase 710,212 shares of common stock. We sold the common shares and warrants for net proceeds of $2.1 million after deducting certain fees due to the placement agent and transaction expenses. Subject to certain beneficial ownership limitations, the warrants became initially exercisable on the six-month anniversary of the issuance date at an exercise price equal to $2.02 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date.

In February 2018, we entered into a securities purchase agreement with certain institutional investors for the sale by us of 4,290,000 shares of our common stock, at a purchase price of $2.10 per share. Concurrently with the sale of the common shares, we also sold warrants to purchase 2,145,000 shares of common stock. We sold the common shares and warrants for net proceeds of $8.2 million after deducting certain fees due to the placement agent and transaction expenses. Subject to certain beneficial ownership limitations, the warrants became exercisable on the six-month anniversary of the issuance date at an exercise price equal to $2.80 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date.

We believe that our existing cash and cash equivalents as of September 30, 2019, will be sufficient to fund our planned operations into the second quarter of 2020, without the issuance of additional equity for cash. Such issuances should extend the funding of our planned operations beyond the second quarter of 2020. Such plans are subject to our stock price, market conditions, changes in planned expenses depending on clinical enrollment progress, the use of drug product or a combination thereof.

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Acquisition and Creation of a Subsidiary

We acquired Moleculin, LLC on May 2, 2016, and, since such date our consolidated financial statements have included the operations of Moleculin, LLC. We account for acquired businesses using the acquisition method of accounting, which requires, among other things, that most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date and that the fair value of acquired in-process research and development ("IPR&D") be recorded on the balance sheet. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the assigned values of the net assets acquired will be recorded as goodwill. We obtained input from third-parties regarding our tangible and intangible assets and other information necessary to measure the fair value of the assets acquired and liabilities assumed in connection with the acquisition of Moleculin, LLC. In June 2018, MBI formed Moleculin Australia Pty. Ltd., ("MAPL"), a wholly owned subsidiary, to begin preclinical development in Australia for WP1732. This may enable us to enjoy the benefits of certain research and development tax credits in Australia. In February 2019, the Company entered into an agreement with Animal Life Sciences, LLC ("ALI"), where the Company has granted a sublicense to ALI to research, develop, make, have made, use, offer to sell, sell, export or import and commercialize certain licensed products and share development data. ALI issued to the Company a 10% membership interest in ALI. In June 2019 ALI became Animal Life Sciences, Inc., incorporated in Nevada.

Research and Development Costs

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

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

Impairment of Long-Lived Assets

Management reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be realizable or at a minimum annually during the fourth quarter of the year. If an evaluation is required, the estimated future undiscounted cash flows associated with the asset are compared to the asset's carrying value to determine if an impairment of such asset is necessary. The effect of any impairment would be to expense the difference between the fair value of such asset and its carrying value.

Warrant Liability

The basis of value of the warrant liability is fair value, which is defined pursuant to Accounting Standards Codification ("ASC") 820 to be "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date". The Company uses the Black-Scholes option pricing model ("BSM") to determine the fair value of its remaining warrants outstanding.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

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

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

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

During the last quarter of fiscal 2016, and as our operational activities increased, management determined that it does not have sufficient segregation of duties within its accounting functions, which is a basic internal control. Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals. Management evaluated the impact of our failure to maintain effective segregation of duties on our assessment of our internal control over financial reporting and has concluded that the control deficiency represents a material weakness. In 2018, management added two accounting positions, added additional fraud controls with regards to our banking systems, and replaced the accounting system with a more robust accounting system that should assist in mitigating this material weakness. Along with these improvements, changes were made in our authorization processes to improve segregation of duties. Certain improvements in segregation of duties are currently being acted upon and addressed, mainly as to the controls on information technology systems.

There has been no change in our internal control over financial reporting during our most recent calendar quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. During the second quarter of 2019, we began scoping and planning the implementation of required internal controls, utilizing outside consultants. In the third quarter of 2019, management increased its accounting staff and added an IT consultant to assist in management's efforts to improve the internal control structure.

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, 2018. 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, 2018 as filed with the SEC.

The timeliness of our clinical trials may be impacted by numerous factors and any delays may adversely affect our ability to execute our current business strategy.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all. If initiation or completion of any of our clinical trials for our product candidates are delayed for any reason, our development costs may increase, our approval process could be delayed, any periods after commercial launch and before expiration of patent protection may be reduced and our competitors may have more time to bring products to market before we do. Any of these events could impair the commercial potential of our product candidates and could have a material adverse effect on our business.

Our clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Clinical testing is expensive, takes many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our product candidates are subject to the risks of failure inherent in biologic drug development. Success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing, even at statistically significant levels. We will be required to demonstrate through clinical trials that our product candidates are safe and effective for use in the target indication before we can obtain regulatory approvals for commercial sale. Companies frequently suffer significant setbacks in late-stage clinical trials, even after earlier clinical trials have shown promising results and most product candidates that commence clinical trials are never approved as products.

If any of our product candidates fail to demonstrate sufficient safety or efficacy, we would experience potentially significant delays in, or be required to abandon our development of the product candidate, which would have a material and adverse impact on our business, prospects, financial condition and results of operations.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we and our collaborators must demonstrate with substantial evidence from well controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for a product candidate are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the United States. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking regulatory

approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Our business and operations would suffer in the event of third-party computer system failures, cyber-attacks on third-party systems or deficiency in our cyber security.

We rely on information technology ("IT") systems, including third-party "cloud based" service providers, to keep financial records, maintain laboratory data, clinical data, and corporate records, to communicate with staff and external parties and to operate other critical functions. This includes critical systems such as email, other communication tools, electronic document repositories and archives. If any of these third-party information technology providers are compromised due to computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication failures, electrical failures, cyber-attacks or cyber-intrusions over the internet, then sensitive emails or documents could be exposed or deleted. Similarly, we could incur business disruption if our access to the internet is compromised and we are unable to connect with third-party IT providers. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, we rely on those third parties to safeguard important confidential personal data regarding our employees and patients enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in a third-party IT provider's operation, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidates could be delayed, or could fail.

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

On July 30, 2019, we entered into a License Modification Agreement with Exploration Invest Pte Ltd pursuant to which we agreed to issue Exploration shares of our common stock valued at $0.5 million (based on the greater of the closing price of the common stock on the date of the agreement or the 10-day average closing price prior to the date of the agreement) in exchange for the modifying certain license agreements. On August 8, 2019, we issued 429,978 shares of common stock to Exploration to satisfy this commitment. The common stock was issued pursuant to Section 4(a)(2) of the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

Exhibit No.	Description
10.1	At Market Issuance Sales Agreement, dated July 23, 2019, by and among the Company and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 1.1 of the Form 8-K filed July 24, 2019)
31.1*	Certification of Principal Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Accounting and Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

SIGNATURES

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

MOLECULIN BIOTECH, INC.

Date: November 12, 2019

By: /s/ Walter V. Klemp

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

Date: November 12, 2019

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 12, 2019

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 12, 2019

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, 2019 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Walter Klemp, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 12, 2019

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, 2019 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan Foster, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 12, 2019

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.