

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **September 30, 2016**

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

(State or Other Jurisdiction of
Incorporation or Organization)

47-4671997

(I.R.S. Employer
Identification No.)

2575 West Belfort, Suite 333, Houston, TX

(Address of Principal Executive Offices)

77054

(Zip Code)

(713) 300-5160

(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of November 9, 2016: 12,054,813

Moleculin Biotech, Inc.
FORM 10-Q
For quarterly period ended September 30, 2016

INDEX

<u>PART I — FINANCIAL INFORMATION</u>		
Item 1.	<u>Financial Statements</u>	3
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4.	<u>Controls and Procedures</u>	22
<u>PART II — OTHER INFORMATION</u>		
Item 1.	<u>Legal Proceedings</u>	23
Item 1A.	<u>Risk Factors</u>	23
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	25
Item 3.	<u>Defaults Upon Senior Securities</u>	26
Item 4.	<u>Mine Safety Disclosures</u>	26
Item 5.	<u>Other Information</u>	26
Item 6.	<u>Exhibits</u>	27
<u>SIGNATURES</u>		28

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

**Moleculin Biotech, Inc.
Balance Sheets**

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current Assets:		
Cash and cash equivalents	\$ 6,183,783	\$ 28,091
Prepaid expenses	244,869	–
Total current assets	6,428,652	28,091
Long-Term Assets:		
Furniture and equipment, net of accumulated depreciation	16,346	–
Intangible assets	11,128,790	–
Total Assets	\$ 17,573,788	\$ 28,091
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 944,997	\$ 322,790
Accounts payable and accrued expenses-related party	37,500	–
Convertible notes payable	297,656	450,000
Total current liabilities	1,280,153	772,790
Long-term payable-related party	50,000	–
Total Liabilities	1,330,153	772,790
Commitment and contingencies		
Stockholders' Equity (Deficit):		
Preferred stock, \$0.001 par value; 5,000,000 authorized, no shares issued and outstanding	–	–
Common stock, \$0.001 par value; 75,000,000 authorized, 12,054,813 and 6,661,000 shares issued and outstanding, respectively	12,055	6,661
Subscription receivable	(3,000)	(3,000)
Additional paid-in capital	19,485,987	–
Accumulated deficit	(3,251,407)	(748,360)
Total Stockholders' Equity (Deficit)	16,243,635	(744,699)
Total Liabilities and Stockholders' Equity (Deficit)	\$ 17,573,788	\$ 28,091

See accompanying notes to the unaudited financial statements.

Moleculin Biotech, Inc.
Statements of Operations
(Unaudited)

	Three Months Ended September 30, 2016	From July 28, 2015 (Inception) Through September 30, 2015	Nine Months Ended September 30, 2016	From July 28, 2015 (Inception) Through September 30, 2015
Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development	496,659	38,409	616,498	38,409
General and administrative	924,041	184,344	1,847,613	184,344
Depreciation	977	-	1,629	-
Total operating expense	<u>1,421,677</u>	<u>222,753</u>	<u>2,465,740</u>	<u>222,753</u>
Loss from operations	(1,421,677)	(222,753)	(2,465,740)	(222,753)
Other expense:				
Interest expense	<u>(10,402)</u>	<u>(1,562)</u>	<u>(37,307)</u>	<u>(1,562)</u>
Net loss	<u>\$ (1,432,079)</u>	<u>\$ (224,315)</u>	<u>\$ (2,503,047)</u>	<u>\$ (224,315)</u>
Net loss per common share - basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.05)</u>	<u>\$ (0.28)</u>	<u>\$ (0.05)</u>
Weighted average common shares outstanding - basic and diluted	<u>11,579,239</u>	<u>4,320,015</u>	<u>9,066,804</u>	<u>4,320,015</u>

See accompanying notes to the unaudited financial statements.

Moleculin Biotech, Inc.
Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30, 2016	From July 28, 2015 (Inception) Through September 30, 2015
Cash Flows from Operating Activities:		
Net loss	\$ (2,503,047)	\$ (224,315)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,629	-
Stock-based compensation	208,939	-
Shares issued for licenses used for research and development	-	2,061
Changes in operating assets and liabilities:		
Prepaid expenses	(244,869)	(23,000)
Accounts payable and accrued expenses	(146,799)	63,010
Accounts payable and accrued expenses – related parties	87,500	19,584
Net Cash Used in Operating Activities	(2,596,647)	(162,660)
Cash Flows from Investing Activities:		
Cash paid for purchase of fixed assets	(10,155)	-
Cash paid for acquisition of Moleculin, LLC, net with cash acquired	(99,638)	-
Net Cash Used in Investing Activities	(109,793)	-
Cash Flows from Financing Activities:		
Proceeds from notes payable	165,000	250,000
Payments on notes payable	(469,939)	-
Proceeds from sale of common stock, net of direct offering costs	9,167,071	-
Net Cash Provided by Financing Activities	8,862,132	250,000
Net change in cash and cash equivalents	6,155,692	87,340
Cash and cash equivalents, at beginning of period	28,091	-
Cash and cash equivalents, at end of period	\$ 6,183,783	\$ 87,340
Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ 47,950	\$ -
Cash paid for income taxes	\$ -	\$ -
Supplemental disclosure of non-cash investing and financing activities:		
Common stock issued to acquire Moleculin, LLC	\$ 9,773,586	\$ -
Common stock issued for conversion of debt	\$ 341,785	\$ -
Shares subscribed	\$ -	\$ 4,600

See accompanying notes to the unaudited financial statements.

Moleculin Biotech, Inc.
Notes to Financial Statements
(Unaudited)

Note 1 – Description of Business and Summary of Significant Accounting Policies

Nature of Business – The terms “MBI” or “the Company”, “we”, “our” and “us” are used herein to refer to Moleculin Biotech, Inc. MBI is a preclinical and clinical-stage pharmaceutical company organized as a Delaware corporation in July 2015 to focus on the development of anti-cancer drug candidates, some 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.

Our lead drug candidate is liposomal Annamycin, which we refer to as Annamycin, an anthracycline intended for the treatment of relapsed or refractory acute myeloid leukemia, or AML. In August 2015, the Company entered into a rights transfer agreement with AnnaMed, Inc. (“AnnaMed”), a company affiliated with certain members of the Company’s management and board of directors, pursuant to which, in exchange for 1,431,000 shares of the Company’s common stock, AnnaMed agreed to transfer any and all data it had regarding the development of Annamycin and the Annamycin IND, including all trade secrets, know-how, confidential information and other intellectual property rights held by AnnaMed. Annamycin has been in clinical trials pursuant to an investigational new drug application, or IND, that had been filed with the U.S. Food and Drug Administration, or FDA. This IND was terminated due to a lack of activity by a prior drug developer. The Company intends to apply for a new IND based on the same data that supported the original IND, updated for subsequent clinical data, and to commence clinical trials for Annamycin funded with the proceeds from our initial public offering which was completed on May 31, 2016.

The Annamycin drug substance is no longer covered by any existing patent protection. We intend to submit patent applications for formulation, synthetic process and reconstitution related to our Annamycin drug product candidate, although there is no assurance that we will be successful in obtaining such patent protection. Independently from potential patent protection, we believe Annamycin will qualify for Orphan Drug status, which could entitle us to market exclusivity of up to 7 and 10 years from the date of approval of a New Drug Application (“NDA”) and Marketing Authorization (“MA”), in the US and the European Union (“EU”), respectively. However, there can be no assurance that such status will be granted. Separately, the FDA may also grant market exclusivity of up to five years for newly approved new chemical entities (of which Annamycin would be one), but there can be no assurance that such exclusivity will be granted or, if granted, for how long.

We have two other drug development projects in progress, one involving a portfolio of small molecules, which we refer to as the WP1066 Portfolio, focused on the modulation of key oncogenic transcription factors involved in the progression of cancer, and the WP1122 Portfolio, a suite of molecules targeting the metabolic processes involved in cancer in general, and glioblastoma (the most common form of brain tumor) in particular. We have been granted royalty-bearing, worldwide, exclusive licenses for the patent and technology rights related to our WP1066 Portfolio and WP1122 Portfolio drug technologies, as these patent rights are owned by MD Anderson.

On August 11, 2015, the Company entered into a rights transfer agreement for WP1122 with IntertechBio Corporation (“IntertechBio”), a company affiliated with certain members of our management, whereby IntertechBio agreed to assign its license or sublicense its license to certain metabolic inhibitor technology owned by MD Anderson. In consideration, the Company issued 630,000 common shares to IntertechBio. IntertechBio agreed to make payments to MD Anderson including an up-front payment, license documentation fee, annual maintenance fee, milestone payments and minimum annual royalty payments for sales of products developed under the license agreement. The Company has assumed the rights and obligations of IntertechBio under the license agreement with MD Anderson. All out-of-pocket expenses incurred by MD Anderson in filing, prosecuting and maintaining the licensed patents have been and shall continue to be assumed by the Company.

The Company filed a registration statement on Form S-1 (which was declared effective on May 2, 2016) with respect to the Company’s initial public offering of shares of its common stock (“IPO”) to fund the development of its technologies. Prior to the declaration of effectiveness of the registration statement on Form S-1, we acquired Moleculin, LLC which was merged with and into MBI, which survived the merger. 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.

Basis of Presentation - Unaudited Interim Financial Information – The accompanying unaudited interim 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 interim 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 financial statements furnished reflect all adjustments (consisting of normal recurring adjustments), which are, in the opinion of management, necessary for a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. These interim unaudited financial statements should be read in conjunction with the audited financial statements of the Company as of December 31, 2015 and for the period from July 28, 2015 (inception) to December 31, 2015 and notes thereto contained in the Registration Statement on Form S-1 filed with the SEC on April 27, 2016.

Use of Estimates in Financial Statement Presentation - The preparation of these financial statements in conformity with accounting principles generally accepted in the United States of America 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 revenues and expenses during the reporting period. Actual results could differ from those estimates.

Acquisition – We acquired Moleculin, LLC (“Moleculin”) on May 2, 2016, and, going forward our financial statements include 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. The estimated fair values of assets acquired and liabilities assumed were determined based on management’s best estimates. Preliminary estimated fair values are subject to measurement period adjustments which represent updates made to the preliminary purchase price allocation based on revisions to valuation estimates in the interim period subsequent to the acquisition and initial accounting date up until the purchase price allocation is finalized which cannot be any later than one year from the acquisition date.

Going Concern - These 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 continued financial support from its stockholders, the ability of the Company to obtain necessary equity financing to continue operations, and the attainment of profitable operations. As of September 30, 2016, the Company has incurred an accumulated deficit of \$3,251,407 since inception, and had not yet generated any revenue from operations. These factors raise substantial doubt regarding the Company’s ability to continue as a going concern. These 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 and other collaborations, strategic alliances and licensing arrangements.

Cash and Cash Equivalents - The Company considers all highly liquid accounts with original maturities of three months or less to be cash equivalents. At September 30, 2016, all of the Company’s cash was deposited in two banks and at December 31, 2015, all of the Company’s cash was deposited in one bank. Periodically, the Company may carry cash balances at financial institutions in excess of the federally insured limit of \$250,000. The amount in excess of the FDIC insurance at September 30, 2016 was \$5,693,442. On October 13, 2016, the Company consolidated all of its cash into one bank with \$2 million and \$3 million deposited into Certificate of Deposit Account Registry Service or CDARS accounts, which are all 100% federally insured, for 4-week and 13-week terms, respectively. The remaining cash is deposited into a checking and money market account.

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 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, the IPR&D assets will be amortized over their estimated useful lives.

We evaluate the recoverability of intangible assets periodically and take into account events or circumstances that warrant revised estimates of useful lives or that indicate that impairment exists. No 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 indicators of potential impairment exist, using a fair-value-based approach.

Beneficial Conversion Feature - From time to time, the Company may issue convertible notes that have conversion prices that create an embedded beneficial conversion feature on the issuance date. A beneficial conversion feature exists on the date a convertible note is issued when the fair value of the underlying common stock to which the note is convertible into is in excess of the remaining unallocated proceeds of the note after first considering the allocation of a portion of the note proceeds to the fair value of any attached equity instruments, if any related equity instruments were granted with the debt. Prior to the Company’s IPO, the Company estimates the fair value of its common stock using the most recent selling price available. The intrinsic value of the beneficial conversion feature is recorded as a debt discount with a corresponding amount to additional paid-in capital. The debt discount is amortized to interest expense over the life of the note using the effective interest method.

Income Taxes - The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of reported 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 must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

Stock-based Compensation - Stock-based compensation expense includes the estimated fair value of equity awards vested during the reporting period. The expense for equity awards vested during the reporting period is determined based upon the grant date fair value of the award and is recognized as expense over the applicable vesting period of the stock award using the straight-line method.

Earnings (Loss) Per Common Share - Basic net earnings (loss) per common share are computed by dividing net earnings (loss) available to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted net earnings (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 have been anti-dilutive. As of September 30, 2016, the Company's potentially dilutive shares included notes convertible to 1,928,899 common shares, options to purchase 510,000 common shares and warrants to purchase 107,802 common shares.

Research and Development Costs - Research and development costs are expensed as incurred.

Subsequent Events - The Company's management reviewed all material events through the date these financial statements were issued for subsequent event disclosure consideration.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standard Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606), which will replace numerous requirements in U.S. GAAP, including industry-specific requirements, and provide companies with a single revenue recognition model for recognizing revenue from contracts with customers. The core principle of the new standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In August 2015, the FASB approved a proposal to defer the effective date of the guidance until annual and interim reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact that this standard will have on its financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Under the new guidance, management will be required to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The provisions of this ASU are effective for annual periods beginning after December 15, 2016, and for annual and interim periods thereafter; early adoption is permitted. The Company is currently evaluating the impact that this standard will have on its financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). ASU 2016-01 affects the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements of financial instruments. ASU 2016-01 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company is currently evaluating the impact that this standard will have on its financial statements.

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. The Company is currently evaluating the impact that this standard will have on its financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation (Topic 718). The new guidance changes the accounting and simplifies various aspects of the accounting for share-based payments to employees. The guidance allows for a policy election to account for forfeitures as they occur or based on an estimated number of awards that are expected to vest. ASU 2016-09 is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact that this standard will have 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 financial statements.

Note 2 – Intangible Assets

The Acquisition of Moleculin, LLC

On May 2, 2016, Moleculin, LLC, a Texas limited liability company, was merged with and into the Company. As a result of the merger, the Company issued to the holders of Moleculin equity interests an aggregate of 999,931 shares of the Company's common stock valued at \$5,999,586 based on the estimated acquisition-date fair value of our common stock of \$6.00 per share, equal to the IPO price announced in our prospectus filed on that date. These shares contain certain trading restrictions. Prior to the Company's acquisition of Moleculin, the Company had loaned \$57,822 to Moleculin which was treated as part of the consideration paid to acquire Moleculin.

As additional consideration payable to the Moleculin unit holders, we agreed pursuant to the merger agreement that if drugs for dermatology indications are successfully developed by us using any of the Existing IP Assets, then the Moleculin, LLC unit holders, in the aggregate, will be entitled to receive a 2.5% royalty on the net revenues generated by such drugs. Any such net revenues would include a deduction for license fees or royalty obligations payable to MD Anderson for such Existing IP Assets. The merger agreement defined "Existing IP Assets" to mean all intellectual property, licensed by us and Moleculin as of the time of the merger, including, without limitation, the intellectual property licensed from MD Anderson under the Patent and Technology License Agreement entered into by and between IntertechBio Corporation and MD Anderson dated April 2, 2012, as amended, and the Patent and Technology License Agreement dated June 21, 2010, as amended, between MD Anderson and Moleculin, LLC, but excluding any intellectual property relating to Annamycin. The right to receive the contingent royalty payments described herein is limited to drugs developed only for dermatology indications, and does not include drugs developed for any other indications. We have no obligation of any nature to pursue the development of any drugs for dermatology indications.

Our acquisition of Moleculin, LLC, occurring prior to our IPO offering, provided us with the rights to the license agreement that Moleculin, LLC had with MD Anderson covering the WP1066 Portfolio. However, Moleculin, LLC had previously granted Houston Pharmaceuticals, Inc. ("HPI"), a related party, an option, which could be exercised at any time, to obtain an exclusive sub-license to develop the WP1066 Portfolio in all non-dermatological fields. Moleculin, LLC had previously pursued development of the WP1066 Portfolio for treatment of psoriasis, however, psoriasis related clinical trials had been terminated. Because WP1066 has shown significant activity against a wide range of tumors, Moleculin, LLC focus prior to the acquisition included the development of drugs for cancer treatment. However, the exclusive sub-license option held by HPI precluded Moleculin, LLC from pursuing drug development related to non-skin cancers, in addition to potentially creating significant intellectual property, clinical and commercialization risks associated with drug development for skin cancers. Re-acquisition of the HPI option was therefore essential for the values of both the WP1066 Portfolio and Moleculin, LLC.

In connection with the acquisition of Moleculin, LLC, we also negotiated on behalf of Moleculin, LLC two agreements with HPI. Under the first agreement, the HPI's option to obtain the aforementioned exclusive sublicense was terminated in exchange for a payment of \$100,000 and the issuance of 629,000 shares of our common stock. Under the second agreement (HPI Out-Licensing Agreement), HPI has received a non-exclusive technology rights and development sublicense under which it may continue its ongoing work to develop the WP1066 Portfolio related to treatment of non-skin cancer. Pursuant to this HPI Out-Licensing Agreement, we agreed to make payments to HPI totaling \$750,000 over a three-year period commencing after the IPO offering in exchange for HPI allowing us to access any data, information or know-how resulting from the research and development conducted by HPI which will be expensed, as incurred, as research and development expense. Notwithstanding our obligation to make the foregoing payments, the HPI Out-Licensing Agreement does not obligate HPI to conduct any specific research or to meet any milestones. Pursuant to the HPI Out-Licensing Agreement, we have the right within three years of the effective date to buy-out from HPI all rights granted to HPI under the agreement for a payment of \$1.0 million. Upon our exercise of the buy-out we will no longer be obligated to make any payments to HPI remaining from the \$750,000 obligation discussed above. If we do not exercise the foregoing buy-out right within three years, the license granted to HPI shall convert into an exclusive license. As such, if we do not exercise the buy-out right for any reason, we will no longer have access to the non-skin cancer uses of the WP1066 Portfolio. As noted above, this will also potentially create risks for the development of skin cancer drugs. We do not intend to set aside and designate cash and cash equivalents in the amount of \$1.0 million to make the buy-out payment. If we ultimately decide to exercise the buy-out right from HPI all rights granted the HPI under the agreement, we will need to raise additional funds to make the buy-out payment. We cannot assure that such additional funding will be available on satisfactory terms, or at all.

The agreements with HPI were executed on May 2, 2016, simultaneously with the closing of the Moleculin, LLC acquisition, and were non-cancelable but contingent on the Company's ability to complete the IPO by June 30, 2016. They became effective on May 31, 2016.

The termination of the HPI option was completed on behalf of Moleculin, LLC, was required to enable the sale of Moleculin, LLC by materializing the value of its most significant asset, and was non-cancelable by either party. Further, the HPI option termination price was determined simultaneously with the acquisition on May 2, 2016 as our IPO price was established at that time. Accordingly, we concluded that this transaction was primarily for the benefit of Moleculin, LLC and its former owners, resulting in control of the underlying intellectual property and thereby increasing the value of Moleculin, LLC intangible assets immediately prior to the closing of its acquisition by us.

The HPI option termination price amounted to \$3,874,000, consisting of 629,000 shares of our common stock valued at the IPO price of \$6.00 per share, and \$100,000 paid in cash in July 2016, and was included in acquisition-date liabilities assumed.

Purchase Price Allocation

The acquisition price was allocated on a preliminary basis, which is subject to change, to the assets acquired and liabilities assumed based upon their estimated fair values and the information available to management. The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date.

Cash	\$	362
Property and equipment		7,820
Intangibles		11,128,790
Total assets acquired	\$	11,136,972
Liability assumed (HPI)		(3,874,000)
Liabilities assumed		(1,205,564)
Net assets acquired/total consideration transferred	\$	6,057,408

The Company is in the process of obtaining input from third-parties regarding its 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; thus the provisional measurements of current assets, property and equipment, intangibles, and liabilities assumed are subject to change, which could be significant. We will finalize the amounts recognized as we obtain the information necessary to complete our analysis. As of this date, management believes all or most of the intangible assets are IPR&D related to the WP1066 Portfolio, and, as such, no amortization has been recorded to date. Any changes to the provisional measurements will be recognized in the period in which they are determined. We expect to finalize these amounts as soon as possible but no later than one year from the acquisition date.

Intangible assets consisted of the following at September 30, 2016 and December 31, 2015:

	September 30, 2016	December 31, 2015
Intangibles acquired from Moleculin, LLC	\$ 11,128,790	\$ —

Unaudited Pro Forma Results of Operations

The following comparative table presents the unaudited condensed pro forma results of operations that reflect the acquisition of Moleculin as if the acquisition had occurred as of the first day of each period presented, adjusted for items that are directly attributable to the acquisition. This information has been compiled from historical financial statements and is not necessarily indicative of the results that actually would have been achieved had the transaction already occurred or that may be achieved in the future.

	For the Three Months Ended September 30, 2016	Pro Forma For the Nine Months Ended September 30, 2016	Pro Forma For the Three Months Ended September 30, 2015	Pro Forma For the Nine Months Ended September 30, 2015
Total operating expenses	\$ (1,421,677)	\$ (2,561,908)	\$ (295,422)	\$ (769,549)
Net loss	\$ (1,432,079)	\$ (2,539,677)	\$ (297,129)	\$ (779,779)
Net loss per common share – basic and diluted	\$ (0.12)	\$ (0.27)	\$ (0.07)	\$ (0.38)
Weighted average outstanding common shares – basic and diluted	11,579,239	9,513,660	4,052,116	2,028,506

The nine months ended September 30, 2016 are adjusted on a pro forma basis to exclude \$145,078 in net interest expense related to the amortization of deferred financing costs and debt discount amortization for Moleculin, LLC's convertible notes. The holders of the convertible notes were issued the Company's common shares upon the Company's acquisition of Moleculin, LLC.

The three months ended September 30, 2015 are adjusted on a pro forma basis to exclude \$112,846 in net interest expense related to the interest expense, the amortization of deferred financing costs and debt discount amortization for Moleculin, LLC's convertible notes.

The nine months ended September 30, 2015 are adjusted on a pro forma basis to exclude \$322,547 in net interest expense related to the interest expense, the amortization of deferred financing costs and debt discount amortization for Moleculin, LLC's convertible notes.

Note 3 – Convertible Notes Payable

On various dates from August 31, 2015 through January 19, 2016, each as amended on March 10, 2016, the Company entered into seven unsecured promissory notes with three separate third party investors. Each note bears interest at 8.0% per annum and was to mature on the earlier of June 30, 2016 or the completion of an IPO of the Company's securities.

Since the completion of the IPO occurred prior to June 30, 2016, these notes were to be automatically converted according to their terms into shares of the Company's common stock at applicable conversion price upon the Company's IPO to the extent and provided that no holder of these notes was or will be permitted to convert such notes to the extent that the holder or any of its affiliates would beneficially own in excess of 4.99% of our common stock after such conversion. Due to this 4.99% limitation, a portion of these notes was not converted at the time of the IPO and the remaining unconverted principal and accrued interest amounts of the effected notes will remain outstanding and will be converted into shares of our common stock at such time as the 4.99% limitation continues to be met. Until such time as the notes are converted into shares of common stock, the maturity date of the notes will automatically be extended and we will not be required to repay the notes or the accrued interest relating to the notes in cash.

The IPO was completed on May 31, 2016. On May 31, 2016, pursuant to the conversion feature of the foregoing notes and with restriction of the 4.99% beneficially owned condition limitation, discussed above, the Company issued 1,166,503 common shares in total, reducing convertible debt principal by \$183,356 and accrued interest by \$17,699. During the three months ended September 30, 2016, an additional 800,057 common shares were issued due to the number of common shares outstanding allowing for conversion of additional shares under the 4.99% beneficially owned condition limitation. This reduced the convertible debt principal by \$133,988 and accrued interest by \$6,742. The remaining convertible debt without consideration of accrued interest as of September 30, 2016, if converted on September 30, 2016, would result in an additional 1,928,899 common shares to be issued.

The convertible notes were analyzed for a beneficial conversion feature on various issuance dates, at which time it was concluded that a beneficial conversion feature did not exist.

The table below represents the shares that are convertible at September 30, 2016 relating to the principal amounts of these convertible notes payable and excludes any shares that are convertible relating to the associated accrued interest:

Issuance Date	September 30, 2016	December 31, 2015	Conversion Rate	Shares Convertible at September 30, 2016
August 31, 2015 (a)	\$ 38,299	\$ 125,000	\$ 0.1299	294,832
September 3, 2015	125,000	125,000	0.1299	962,279
October 4, 2015(a)(c)	30,280	147,000	0.20	151,402
October 4, 2015(b)	–	3,000	0.20	–
October 28, 2015(b)	–	50,000	0.20	–
January 14, 2016(c)	21,577	–	0.20	107,886
January 19, 2016	82,500	–	0.20	412,500
Total	<u>\$ 297,656</u>	<u>\$ 450,000</u>		<u>1,928,899</u>

(a) Debt partially converted on May 31, 2016 and on August 19, 2016.

(b) Debt fully converted to common shares on May 31, 2016.

(c) Debt partially converted on September 1, 2016.

The common shares relating to the above mentioned convertible notes payable contain the following trading restrictions: (a) beginning 90 days after the initial closing of our IPO and until the one-year anniversary of the initial closing of the IPO, the holder of the note will be able to sell 1% of the number of shares of common stock underlying the note on a monthly basis, subject to a maximum sale on any trading day of 4% of the daily volume; (b) if the common stock price is over \$7.00 per share for five consecutive trading days then the holder of the note can sell up to 3% of the number of shares of common stock underlying the note on a monthly basis, subject to a maximum sale on any trading day of 4% of the daily volume; (c) if the common stock price is over \$10.00 per share for five consecutive trading days then the holder of the note can sell up to an additional 5% of the number of shares of common stock underlying the note on a monthly basis, subject to a maximum sale on any trading day of 7% of the daily volume; and (d) if the common stock price is over \$14.00 per share then the holder of the note is not restricted from making any sales until such time as the common stock price falls back below \$14.00 per share; and (b) thereafter, until the two-year anniversary of the initial closing of IPO, the holder of the note can sell on any trading day 10% of the daily volume; provided that if the common stock price is over \$10.00 per share then the holder of the note is not restricted from making any sales until such time as the common stock falls back below \$10.00 per share. The foregoing lock-up restrictions relate to public sales and do not restrict the transfer of the shares privately, if permitted by applicable law, provided the acquirer of the shares agrees to comply with the above restrictions with respect to any public sales.

Note 4 – Equity

On May 2, 2016, the Company amended and restated its certificate of incorporation to increase the number of shares authorized to 80,000,000 of which 5,000,000 shares of preferred stock are authorized and 75,000,000 shares of common stock are authorized.

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock. Our 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, 2016, there was no designated preferred stock.

Common Stock

On May 31, 2016, the Company completed its IPO and sold 1,540,026 shares of the Company's common stock. The IPO price per share was \$6.00. The Company received net proceeds of \$8,464,183 after deducting underwriting discounts, commissions and direct offering expenses payable by us. Pursuant to our agreement with our underwriters, as additional compensation, we issued the underwriters warrants to purchase 107,802 shares of common stock exercisable for a period of 5 years from date of issuance at an exercise price of \$7.50 per share. The relative fair value of these warrants was \$374,763 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.39% (2) expected life of 5 years, (3) expected volatility of 80.61%, and (4) zero expected dividends.

In August 2015, the Company agreed to issue 4,600,000 shares of common stock to its director, officers and founders for subscriptions of \$4,600 cash to be received. As of September 30, 2016, the Company had not collected the proceeds for \$3,000 of the subscriptions.

During the period from January 1, 2016 through May 2, 2016, the Company sold 234,296 common shares for \$702,888. These shares are subject to the following lock-up agreement, from and after the later of six months after issuance or 90 days from the effective date of our IPO registration statement until the one-year anniversary thereof, (a) the holder of the shares can sell up to 10% of the purchased shares per month, subject to a maximum sale on any trading day of 8% of the daily volume of the common stock; (b) if the common stock price is over \$7.00 per share for five consecutive trading days then the holder of the shares can sell up to 20% of the purchased shares per month, subject to a maximum sale on any trading day of 10% of the daily volume of the common stock; and (c) if the common stock price is over \$12.00 per share then the holder of the shares is not restricted from making any sales until such time as the common stock price falls back below \$12.00 per share.

On June 20, 2016, the Company agreed to issue 24,000 shares of common stock to PCG Advisory Group, the Company's investor relations firm, for services provided. The fair value of these shares was \$157,688 based on the market price on the grant date.

Adoption of 2015 Stock Plan

On December 5, 2015, the Board of Directors of the Company approved the Company's 2015 Stock Plan, which was amended on April 22, 2016. 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 2,500,000 shares. The awards under the 2015 Stock Plan can be in the form of stock options, stock awards or stock unit awards. The following is a summary of option activities for the nine months ended September 30, 2016:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2015	200,000	\$ 0.20		
Granted	460,000	5.83		
Cancelled	(150,000)	0.20		
Outstanding, September 30, 2016	<u>510,000</u>	\$ 5.28	9.29	\$ 275,500
Exercisable, September 30, 2016	<u>50,000</u>	\$ 0.20	3.67	\$ 275,500

During the nine months ended September 30, 2016, the Company granted an employee and its board of directors options, in the aggregate, to purchase 460,000 shares of the Company's common stock with an exercise price ranging from \$5.71 per share to \$5.85 per share, a term of 10 years, and a vesting period of 3 to 4 years. The exercise price was based upon the closing price of the stock on the day of the grant. The options have an aggregated fair value of \$1,725,052 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount of 1.30% (2) expected lives of 6 to 6.25 years, (3) expected volatility of 70.18% to 70.44%, and (4) zero expected dividends. During the nine months ended September 30, 2016, the Company recorded \$51,251 in stock-based compensation in relation to these options. The Company entered into a separation agreement with its former Chief Financial Officer in October 2016 and as part of the agreement, options to purchase 150,000 shares of common stock issued to the former Chief Financial Officer were cancelled and the vesting was accelerated on the remaining options to purchase 50,000 shares of common stock.

Note 5 – Income Taxes

As of September 30, 2016, the Company had an operating loss carry forward of approximately \$3,343,000 which expires commencing in 2035. The value of these carryforwards depends on the Company's ability to generate taxable income. A change in ownership, as defined by federal income tax regulations, could significantly limit the Company's ability to utilize our net operating loss carryforwards. Additionally, because federal tax laws limit the time during which the net operating loss carryforwards may be applied against future taxes, if the Company fails to generate taxable income prior to the expiration dates the Company may not be able to fully utilize the net operating loss carryforwards to reduce future income taxes. The Company has cumulative losses and there is no assurance of future taxable income, therefore, valuation allowances have been recorded to fully offset the deferred tax asset at September 30, 2016.

Note 6 – Commitments and Contingencies

MD Anderson – IntertechBio Agreement

On August 11, 2015, the Company acquired the rights and obligations under the Patent and Technology License Agreement entered into between IntertechBio and MD Anderson dated April 2, 2012. Pursuant to the agreement, IntertechBio obtained a royalty-bearing, worldwide, exclusive license to intellectual property including patent rights related to the Company's drug product candidate, WP1122. Under the agreement, IntertechBio agreed to pay annual maintenance fee in the amount of \$10,000 on the first anniversary of the effective date of the agreement, \$20,000 on the second anniversary of the effective date of the agreement, \$40,000 on the third anniversary of the effective date of the agreement, \$60,000 on the fourth anniversary of the effective date of the agreement, \$80,000 on the fifth anniversary of the effective date of the agreement and \$100,000 on the sixth anniversary of the effective date of the agreement, except that such payments will no longer be due upon the first sale of a licensed product. Under the agreement, IntertechBio also agreed to make a minimum annual royalty payment in the amount of \$200,000 for the first anniversary following the first sale of a licensed product, \$400,000 for the second anniversary following the first sale of a licensed product, and \$600,000 for the third year following the first sale of a licensed product. IntertechBio also agreed to make certain milestone payments. Pursuant to an amendment on October 19, 2015, the Company will pay milestone payments as follows:

Phase	Amount
Commencement of Phase II Study for a licensed product	\$ 200,000
Commencement of Phase III Study for a licensed product	\$ 250,000
Filing of a New Drug Application for a licensed product	\$ 400,000
Receipt of market approval for a licensed product	\$ 500,000

Per the October 2015 amendment to the agreement, MD Anderson has the right to terminate the license agreement if (i) a preclinical toxicology program for a licensed product is not initiated within one year of the effective date of the amendment (which has occurred), (ii) an investigational new drug application is not filed with the Food and Drug Administration for a Phase I study for a licensed product within three years of the effective date of the amendment, or (iii) a Phase I study for a licensed product is not commenced within five years of the effective date of the amendment. The agreement will expire upon the expiration of the licensed intellectual property. The rights obtained by the Company pursuant to the 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. All out-of-pocket expenses incurred by MD Anderson in filing, prosecuting and maintaining the licensed patents have been and shall continue to be assumed by the Company.

On October 8, 2015, IntertechBio Corporation entered into a letter agreement with MD Anderson wherein MD Anderson agreed to receive past due maintenance fees and patent expenses of \$98,108 owed by IntertechBio Corporation in four installments. The past due amount is related to certain metabolic inhibitor technology license that was assigned to the Company by IntertechBio Corporation and was owed by IntertechBio Corporation prior to the Company's acquisition of the license. Pursuant to the letter, IntertechBio Corporation also agreed to pay \$65,504 in patent fees to a law firm. In order to have the license in good standing, the Company agreed to pay MD Anderson the \$98,108 and the \$65,504 in patent fees to a patent law firm on behalf of IntertechBio Corporation. As of December 31, 2015, \$45,000 of the past due amount to MD Anderson and \$42,504 in patent fees to a patent law firm were still outstanding and were included in accounts payable and accrued liabilities. On April 15, 2016, the Company entered into a letter agreement with MD Anderson where MD Anderson agreed to receive the remaining outstanding amount on or before the earlier of a) May 31, 2016 or b) four days after the Company's completion of the IPO. These amounts were paid prior to or on May 31, 2016.

MD Anderson – Patent & Technology License Agreement

Upon the Company's acquisition of Moleculin, LLC on May 2, 2016, we obtained a royalty-bearing, worldwide, exclusive license to intellectual property rights, including patent rights related to our WP1066 drug product candidate from MD Anderson through a Patent and Technology License Agreement Moleculin, LLC entered with MD Anderson on June 21, 2010 (the "Moleculin License Agreement"). Under the Moleculin License Agreement, Moleculin, LLC obtained the right to manufacture, have manufactured, use, import, offer to sell or sell products worldwide for any indication under the licensed intellectual property with the right to sublicense. In consideration, Moleculin, LLC agreed to 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. Specifically, under the Moleculin License Agreement, Moleculin, LLC agreed to pay a nonrefundable upfront documentation fee and an annual maintenance fee in the amount of \$20,000 on June 21, 2011, which has and shall increase in \$10,000 increments on an annual basis thereafter up to a maximum of \$100,000, except that such payments will no longer be due upon marketing approval in any country of a licensed product. Under the Moleculin License Agreement, Moleculin, LLC also agreed to make a minimum annual royalty payment to MD Anderson in the amount of \$200,000 after the first sale of a licensed product.

Upon completion of our acquisition of Moleculin, LLC, we assumed the rights and obligations of Moleculin, LLC. However, the rights we have obtained pursuant to the assignment of the Moleculin License 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. All out-of-pocket expenses incurred by MD Anderson in filing, prosecuting and maintaining the licensed patents have been and shall continue to be assumed by us.

On October 8, 2015, Moleculin, LLC entered into a letter agreement with MD Anderson for Moleculin, LLC's past due fees to MD Anderson in the amount of \$691,186 of which \$300,000 had been paid prior to the letter agreement. Pursuant to the letter agreement, MD Anderson agreed to receive the remaining past due fee in three installments: a) \$125,000 on October 31, 2015; b) \$175,000 on January 31, 2016; and c) \$91,186 on April 30, 2016. Moleculin, LLC paid \$125,000 to MD Anderson on November 2, 2015.

On October 19, 2015, the agreement was amended for the milestone payments. The amended milestone payments are as follows: (i) commencement of Phase III Study for first licensed drug/product within the United States, Europe, China or Japan - \$150,000; (ii) submission of the first NDA within the United States - \$500,000; and (iii) receipt of first marketing approval for sale of a license product in the United States \$600,000.

On January 28, 2016, the Company and Moleculin, LLC entered into a letter agreement with MD Anderson where MD Anderson agreed to receive the remaining outstanding amount on or before the earlier of April 30, 2016 or four days after our IPO. This date was amended and per the amended agreement, the Company paid the outstanding Moleculin, LLC fees on May 31, 2016 in the amount of \$306,186.

Bonwick Capital Partners LLC

On January 22, 2016, as amended on February 15, 2016, the Company entered into a letter agreement with Bonwick Capital Partners LLC. ("Bonwick") to engage Bonwick as an exclusive financial advisor of the Company. Pursuant to the agreement, the Company agreed to: a) pay success fees equal to 7% of the gross proceeds from any form of financing; and b) issue five-year warrants to purchase 7% of the Company's equity securities sold with a cashless exercise provision, exercisable at 125% of the price per share of the Company's common stock paid by investors in the transaction. In addition, the Company agreed to reimburse Bonwick for all of its out-of-pocket expenses incurred in connection with the offering, not to exceed \$25,000, and fees and expenses of their counsel not to exceed \$100,000. Upon completion of the Company's IPO, the Company paid Bonwick a \$50,000 advisory fee.

Bonwick is also entitled to a success fee as set forth above if the Company completes a financing with parties introduced by Bonwick prior to the termination agreement or during the 6-month period following the termination of the agreement, which occurred on August 2, 2016. In connection with the Company's IPO, Bonwick received a success fee of \$646,872, warrants to purchase 107,802 shares of common stock at an exercise price of \$7.50 per share, and \$6,266 for reimbursement of expenses.

Houston Pharmaceuticals, Inc.

Our acquisition of Moleculin, LLC, occurring prior to our IPO offering, provided us with the rights of the license agreement that Moleculin, LLC had with MD Anderson covering the WP1066 Portfolio. As discussed in Note 2, we are obligated to make payments to HPI totaling \$750,000 over a three-year period commencing after the IPO offering in exchange for HPI allowing us to access any data, information or know-how resulting from the research and development conducted by HPI. Pursuant to the HPI Out-Licensing Agreement, we have the right within three years of the date we enter into the agreement to buy-out from HPI all rights granted to HPI under the agreement for a payment of \$1.0 million. Upon our exercise of the buy-out we will no longer be obligated to make any payments to HPI remaining from the \$750,000 obligation discussed above. We will need to raise additional funds to make the buy-out payment. We cannot assure that such additional funding will be available on satisfactory terms, or at all.

Employment Agreement

On October 13, 2016, the Company and its Chief Executive Officer entered into an employment agreement, pursuant to which, during the period commencing June 1, 2016 and ending June 1, 2017, \$12,500 per month of the compensation is deferred. The deferred compensation shall be payable in a lump sum on the earlier of the termination of the employment agreement or June 1, 2019. As of September 30, 2016, deferred compensation of \$50,000 was included in long-term payable-related party.

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

FORWARD-LOOKING STATEMENT NOTICE

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") 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. Factors that may cause differences between actual results and those contemplated by forward-looking statements include, but are not limited to:

- our ability to obtain additional funding to develop our product candidates;
- the need to obtain regulatory approval of our product candidates;
- the success of our clinical trials through all phases of clinical development;
- compliance with obligations under intellectual property licenses with third parties;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to commercialize our product candidates;
- market acceptance of our product candidates;
- competition from existing products or new products that may emerge;
- potential product liability claims;
- our dependency on third-party manufacturers to supply or manufacture our products;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- 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.

Highlights

We are a preclinical and clinical-stage pharmaceutical development company organized as a Delaware corporation in July 2015 to focus on the development of anti-cancer drug candidates. We have three drug development projects. Our lead drug candidate is liposomal Annamycin, which is referred to as Annamycin, an anthracycline intended for the treatment of relapsed or refractory acute myeloid leukemia, or AML. Annamycin has been in clinical trials pursuant to an investigational new drug application, or IND, that had been filed with the U.S. Food and Drug Administration, or FDA. Due to a lack of development activity by a prior drug developer, this IND was terminated, however we intend to apply for a new IND based on the same data that supported the original IND, updated for subsequent clinical data, and to commence a clinical trial for Annamycin.

We have two other drug development projects in progress. One of them involves a collection of small molecules we refer to as the WP1066 Portfolio that was obtained via our merger with Moleculin, LLC ("Moleculin") and is focused on the modulation of key regulatory transcription factors involved in the progression of cancer. The other, which we call the WP1122 Portfolio, is a suite of molecules targeting the metabolic processes involved in cancer in general, and glioblastoma in particular that we acquired from IntertechBio Corporation. Both of these technologies are licensed on a worldwide exclusive basis from The University of Texas M.D. Anderson Cancer Center, or MD Anderson.

Overview

MBI was founded in 2015 in order to combine and consolidate the development efforts involving several anti-cancer technologies, some of which are 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, we created a co-development agreement with Houston Pharmaceuticals, Inc., or HPI, which culminated with the merger of Moleculin and MBI coincident with our initial public offering allowing us to gain control of the WP1066 Portfolio.

AnnaMed was formed in 2012 to take over the development of Annamycin from a prior drug development company, Callisto Pharmaceuticals, Inc., or Callisto. Callisto ceased development work on Annamycin leading to the termination of its IND by the FDA. In order to satisfy unmet license obligations, Callisto agreed to transfer all available Annamycin data to AnnaMed, which data we intend to now use to apply for a new IND.

IntertechBio was formed in 2009 to license and begin development on the WP1122 Portfolio. In August 2015, IntertechBio agreed to assign all license rights to us in exchange for 630,000 shares of our common stock.

Moleculin was formed in 2006 and has been working to develop the WP1066 Portfolio it licensed from MD Anderson. On May 2, 2016, Moleculin was merged with and into MBI. As a result of the merger, we issued the holders of Moleculin equity interests and convertible notes an aggregate of approximately 999,931 shares of our common stock.

Since Moleculin commenced operations in 2006, substantially all of its efforts have been focused on research, development and the advancement of the WP1066 Portfolio. Moleculin has not generated any revenue from product sales and, as a result, has incurred significant losses.

Neither Moleculin nor MBI has manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, Moleculin currently utilizes third-party clinical research organizations to carry out clinical trials. Neither Moleculin nor MBI have a sales organization.

Recent Business Developments

Accelerated Plan for Clinical Drug Production – The Company announced on October 7, 2016, that it had secured an agreement with Dermin Sp. Zo. O. (“Dermin”) to utilize Dermin’s supply of Annamycin for its upcoming clinical trial, substantially reducing the expenditures required of Moleculin for drug product and shortening the time required to produce clinical supplies. The Company believes that this is an important agreement and key milestone to be reached and that it reduces the potential for drug production to negatively impact its clinical timeline. With this agreement in place, the Company’s drug product expense for upcoming clinical trials should be below previous estimates.

Moleculin previously licensed Annamycin to Dermin within a limited region in Europe, enabling Dermin to deploy Polish grant funds toward producing Annamycin. The agreement reached between the two companies allows Moleculin to utilize this Annamycin in its upcoming clinical trials rather than having to produce new Annamycin for its own use. The Company believes Dermin benefits from a data sharing arrangement giving it access to Moleculin’s clinical data on a faster timeline than it would be able to develop on its own.

Updated Plan for Clinical Trials for Annamycin – On October 20, 2016, the Company announced in a conference call that it had identified some significantly positive findings from its detailed review of the last clinical trial for Annamycin by a prior developer, which has given rise to a modification of its own clinical development plan.

As the Company previously disclosed, a prior developer had conducted a clinical trial with Annamycin, but then subsequently failed to maintain their IND with the FDA. The Company had previously indicated that its plan was to conduct a detailed review of the clinical results generated by that prior developer. The Company would then use those results to reestablish an IND in order to continue clinical trials of Annamycin. However, the Company announced recently that, in the course of its review, it identified that Annamycin may have greater potential for efficacy than the Company originally believed, based on an unexpected potential opportunity to increase the drug’s Maximum Tolerable Dose (“MTD”).

In particular, the Dose Limiting Toxicities (“DLTs”) reported in that previous trial that led to the establishment of the current MTD of 150 mg/m² were all from patients who had an unusually high number of first-line induction therapy failures prior to being treated with Annamycin. Specifically, of the three patients in the last clinical trial who experienced these DLTs, one of them had failed nineteen prior induction therapy attempts, another had failed sixteen and the other had failed fifteen before being enrolled in the trial. The Company has concluded from its review of this data that, if the heavily treated patients are excluded from the data set, the MTD could have been closer to 250 mg/m², substantially higher than the level that was actually set by this previous trial.

The Company views this as an encouraging development because it means it may have an opportunity to increase the MTD for its next trial from 150 mg/m² to 200 or even 250 mg/m². If that turns out to be the case, the Company believes it could increase the chance for positive outcomes in its next trial.

With the discovery that the Company may be able to increase its MTD, the Company determined to adjust its clinical strategy by adding in a Phase I arm to its next Phase II trial, which will add some expense to its development effort. However, the Company believes the money saved by utilizing the Dermin drug inventory (discussed above) will offset this added expense. The Company believes this change in strategy will add several months to the eventual final approval of the drug, however, the Company believes that it remains on track to generate useful Phase II data by the second half of next year.

FDA Guidance Regarding Annamycin IND – On November 17, 2016, the Company announced it had received verbal positive guidance from the FDA regarding its planned IND submission indicating that the Company may incorporate by reference the IND established by a prior developer. The Company has indicated in previous disclosures that it expected to begin its next clinical trial by the first half of 2017, however this development may reduce that time frame by several months. The Company has submitted a pre-IND briefing document to the FDA along with key questions regarding its clinical development plan and a request for a meeting, if the FDA deems it necessary. The FDA recently indicated in writing that it intends to provide written responses to the Company by December 6, 2016 and that it does not believe a live meeting is necessary. Once those written responses are received, the Company will adjust its final IND submission document accordingly and submit for final FDA review. IND submissions are normally reviewed within 30 days of filing.

Update on WP1066 - A clinician at MD Anderson has advised the Company that she is proceeding with a physician-sponsored IND for WP1066 treatment of brain tumors. The Company is not participating nor has influence on this IND process. The clinician has submitted an IND to the FDA and has indicated that this IND is on hold until documentation of Good Manufacturing Process or GMP production of WP1066 can be presented to the FDA.

Advancement of Preclinical Testing for Brain Tumors with WP1122 – On October 25, 2016, the Company announced promising initial results of the preclinical toxicology work on WP1122, the Company's unique inhibitor of glucose metabolism, which is an important driver of glycolytic brain tumor progression and survival. The Company views this as an important step toward future clinical trials for WP1122. A similar chemical structure to that which turns morphine into heroin has been used to allow WP1122 to successfully enter the brain and increase circulation time. The Company indicated that preliminary escalating single dose toxicity testing in mice (oral administration) was successfully completed and even at the highest possible dose, no toxic death was observed. In multiple therapeutic doses, WP1122 was well tolerated during intense twice-daily oral dosing.

The Company believes moving forward with preclinical toxicology is the key to its ability to generate proof of concept in humans. The Company had previously announced the presentation of promising preclinical data in July 2016, supporting the potential for using WP1122 as a treatment for glioblastoma.

Appointment of New Chief Financial Officer - On August 22, 2016, the Company announced the appointment, effective August 19, 2016, of Jonathan P. Foster as Executive Vice President and Chief Financial Officer. Effective on August 19, 2016, Mr. Foster assumed the duties of CFO from Louis Ploth, Jr., who had come out of retirement in 2015 to help guide the new company through its initial public offering.

Mr. Foster joined Moleculin from InfuSystem Holdings, Inc., an NYSE MKT listed company and a leading national provider of infusion pumps and related services to the healthcare industry in the United States and Canada, primarily related to the treatment of cancer, where he served as Executive Vice President and Chief Financial Officer, since 2012. He brings more than 30 years of financial experience holding a variety of executive and senior financial positions with public, private, and start-up to large corporate and international companies.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Research and Development Costs

We record accrued expenses for estimated costs of our research and development activities conducted by third-party service providers, which include the conduct of pre-clinical studies and 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 statement 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, the number of patients enrolled and the rate of patient enrollment 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.

Acquisition

Our financial statements include the operations of an acquired business after the completion of the acquisition. 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 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 is recorded as goodwill. The estimated fair values of assets acquired and liabilities assumed, were determined based on management's best estimates. Preliminary estimated fair values are subject to measurement period adjustments which represent updates made to the preliminary purchase price allocation based on revisions to valuation estimates in the interim period subsequent to the acquisition and initial accounting date up until the purchase price allocation is finalized which cannot be any later than one year from the acquisition date.

The Company is in the process of obtaining input from third-parties of its tangible and intangible assets and other information necessary to measure the fair value of the assets acquired and liabilities assumed and their resulting allocation; thus the provisional measurements of current assets, property and equipment, intangibles, and liabilities assumed are subject to change, which could be significant. We will finalize the amounts recognized as we obtain the information necessary to complete the analysis. We expect to finalize these amounts as soon as possible but no later than one year from the acquisition date.

Results of Operations –

The Company was formed on July 28, 2015; therefore the financial information for 2015 is not comparable to the financial results of the three and nine months ended September 30, 2016. The following table sets forth, for the periods indicated, data derived from our statement of operations:

	Three Months Ended September 30, 2016 <u>(Unaudited)</u>	From Inception through September 30 2015 <u>(Unaudited)</u>	Nine Months Ended September 30, 2016 <u>(Unaudited)</u>	From Inception through September 30, 2015 <u>(Unaudited)</u>
Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development	496,659	38,409	616,498	38,409
General and administrative	924,041	184,344	1,847,613	184,344
Depreciation	977	-	1,629	-
Total operating expense	<u>1,421,677</u>	<u>222,753</u>	<u>2,465,740</u>	<u>222,753</u>
Loss from operations	(1,421,677)	(222,753)	(2,465,740)	(222,753)
Other expense:				
Interest expense	<u>(10,402)</u>	<u>(1,562)</u>	<u>(37,307)</u>	<u>(1,562)</u>
Net loss	<u>\$ (1,432,079)</u>	<u>\$ (224,315)</u>	<u>\$ (2,503,047)</u>	<u>\$ (224,315)</u>

Three Months Ended September 30, 2016 compared to three months ended September 30, 2015

Research and Development Expense. Research and development expense was \$496,659 and \$38,409 for the three months ended September 30, 2016 and 2015, respectively. The increase of approximately \$458,000 mainly represents accrued license fees to MD Anderson for approximately \$40,000, \$37,500 for research performed by HPI, and approximately \$228,000 related to MD Anderson sponsored research. We expect to incur increased research and development costs in the future as our product development activities expand.

General and Administrative Expense. General and administrative expense was \$924,041 and \$184,344 for the three months ended September 30, 2016 and 2015, respectively. The expense increase of approximately \$740,000 was mainly attributable to additional payroll and related expenses of approximately \$459,000 related to a full three months of our Chief Financial Officer's, Chief Operating Officer's and Chief Executive Officer's salaries and compensation for our Board of Directors. Also, included in this quarter's expense was \$118,000 related to the severance of the former Chief Financial Officer. The Company also incurred approximately \$289,000 of expenses related to investor relations, audit and accounting, and insurance costs.

Interest Expense. Interest expense included expense accrued on our convertible promissory notes issued in 2015 and 2016 bearing interest at the rate of 8% per annum.

Net Loss. The net loss for the three months ended September 30, 2016 was \$1,432,079 which included non-cash expenses of \$48,420 (\$977 for depreciation and \$47,443 for stock based compensation) and a one-time expense of \$118,000 related to the severance of the former Chief Financial Officer. This loss for the period is a significant increase from the loss for the three months ended September 30, 2015 of \$224,315 as the Company had, at that time, just begun operations.

Nine Months Ended September 30, 2016 compared to the period from inception through September 30, 2015

Research and Development Expense. Research and development expense was \$616,498 and \$38,409 for the nine months ended September 30, 2016 and for the period from inception to September 30, 2015, respectively. The increase of approximately \$578,000 mainly represents accrued license fees to MD Anderson for approximately \$92,000, \$37,500 for research performed by HPI, and approximately \$228,000 related to MD Anderson sponsored research. We expect to incur increased research and development costs in the future as our product development activities expand.

General and Administrative Expense. General and administrative expense was \$1,847,613 and \$184,344 for the nine months ended September 30, 2016 and for the period from inception to September 30, 2015, respectively. The expense increase of approximately \$1,663,000 was mainly attributable to additional payroll and related expenses of approximately \$551,000 related to compensation of our Chief Financial Officer's, Chief Operating Officer's and Chief Executive Officer's salaries and compensation for our Board of Directors in during the third quarter of 2016. The Company also incurred approximately \$951,000 of expenses related to investor relations, legal, audit and accounting, and insurance costs.

Interest Expense. Interest expense included expense accrued on our convertible promissory notes issued in 2015 and 2016 bearing interest at the rate of 8% per annum.

Net Loss. The net loss for the nine months ended September 30, 2016 was \$2,503,047 which included non-cash expenses of \$210,568 (\$1,629 for depreciation and \$208,939 for stock based compensation and other stock based expenses) and a one-time expense of \$118,000 related to the severance of the former Chief Financial Officer. This loss for the period is a significant increase from the loss for the period from inception to September 30, 2015 of \$224,315 as the Company had, at that time, just begun operations.

Liquidity and Capital Resources

As of September 30, 2016, we had \$6,183,783 in cash. During the period from January 1, 2016 through May 2, 2016, we sold 234,296 of common stock for \$702,888. On May 31, 2016, we completed our initial public offering, pursuant to which we sold 1,540,026 shares of our common stock at \$6.00 per share for net proceeds of \$8,464,183 after deducting underwriting discounts and commissions and direct offering expenses payable by us. We believe that our existing cash and cash equivalents as of September 30, 2016 will be sufficient to fund our planned operations to the end of the third quarter of 2017, which includes our revised clinical trial plan for Annamycin.

We do not expect to 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.

The following table sets forth the primary sources and uses of cash for the period indicated:

	For the Nine Months Ended September 30, 2016 <u>(Unaudited)</u>
Net cash used in operating activities	\$ (2,596,647)
Net cash used in investing activities	(109,793)
Net cash provided by financing activities	<u>8,862,132</u>
Net increase in cash and cash equivalents	<u>\$ 6,155,692</u>

Cash used in operating activities

Net cash used in operating activities was \$2,596,647 for the nine months ended September 30, 2016 and mainly included payments made for payroll, travel, insurance and professional fees to our consultants, attorneys and accountants for services related to our becoming a publicly traded company and related filing fees, along with payments made to MD Anderson for license and maintenance fees. Additionally, prepayments were made for directors and officers insurance.

Cash used in investing activities

Net cash used in investing activities was \$109,793 for the nine months ended September 30, 2016 and primarily represents the cash paid to acquire Moleculin, LLC.

Cash provided by financing activities

Net cash provided by financing activities was \$8,862,132 for the nine months ended September 30, 2016. We received \$8,464,183 net proceeds from our IPO stock issuance, \$702,888 from issuance of common shares at \$3 per share, and \$165,000 from issuance of convertible notes. Net cash used in financing activities included approximately \$470,000 for payments of notes payable.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not required by smaller reporting companies.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including our chief executive officer (our principal executive officer) and chief financial officer (our principal financial and accounting officer), we conducted an evaluation of the effectiveness, as of September 30, 2016, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based upon such evaluation, our chief executive officer and chief financial officer have concluded that, as of September 30, 2016, our disclosure controls and procedures were not effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

We continue to improve certain controls over the Company's financial reporting, although limitations of available funds and headcount make improvements difficult. Our initiatives include adding headcount to assist with financial reporting, improvement in the segregation of duties, and the continued use of outside counsel to aid in the processing and review of agreements and ensuring proper disclosures are being made. However, even with these improvements one or more material weaknesses or significant deficiencies could be present and result in errors in our financial statements.

Changes in Internal Control over Financial Reporting. In preparing this report, management determined that a material weakness existed in its internal control over financial reporting, specifically over accounting for business combinations, that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Management has engaged an outside firm to assist with such accounting.

On November 14, 2016, our Audit Committee, after discussion with management and our independent registered public accountants, determined that our unaudited consolidated financial statements for the quarter ended June 30, 2016, as reported in our Quarterly Report on Form 10-Q filed on August 15, 2016 should no longer be relied upon due to an error identified therein, and that a restatement of these financial statements is required. We identified certain non-cash errors due to an error in the accounting for the business combination of Moleculin, LLC. We have filed a Form 10-Q/A for the quarter ended June 30, 2016 reflecting such corrections in errors.

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 our prospectus filed pursuant to Rule 424(b)(4) on May 3, 2016 with the SEC, which are incorporated herein by reference. The risks described in the prospectus are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Except as updated below, there have been no material changes from the risk factors previously disclosed in our reports as filed with the SEC. The risk factors below supersede, in its entirety, the risk factors set forth in Item 1A in our Quarterly Report on form 10-Q for the second quarter of 2016.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We intend to use the proceeds from our previous offering to advance Annamycin clinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital in order to complete clinical development and commercialize Annamycin. If the FDA requires that we perform additional nonclinical studies or clinical trials, or if we determine, as we did in October 2016, that additional clinical trials are required for Annamycin, our expenses would further increase beyond what we currently expect and the anticipated timing of any potential approval of Annamycin would likely be delayed. Further, there can be no assurance that the costs we will need to incur to obtain regulatory approval of Annamycin will not increase.

We will continue to require substantial additional capital to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual amount of funding we will require to complete research and development and commercialize our products under development.

The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- whether our updated plan for clinical trials will be completed on a timely basis and, if completed, will be successful in producing useful clinical data in 2017;
- whether we are successful in obtaining a Special Protocol Assessment, or SPA, with the FDA related to Annamycin;
- the progress, costs, results of and timing of our clinical trials for Annamycin;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the progress of our collaborative drug development partners, which is dependent upon their continued access to grant funding;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of our product candidates;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and enforce the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to rely on data to be generated by our sublicensee partner, Dermis;
- our need and ability to rely on data and drug product for clinical trials to be generated by our sublicensee partner, Dermis;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing drug candidates and new product approvals;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and

the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Some of these factors are outside of our control. Based upon our currently expected level of operating expenditures, we believe that we will be able to fund our operational plan through the third quarter of 2017. This period could be shortened if there are any significant increases in planned spending on development programs or more rapid progress of development programs than anticipated. We do not believe that our existing capital resources are sufficient to enable us to complete the development and commercialization of Annamycin, if approved, or to initiate any clinical trials or additional development work needed for any other drug candidates, other than as described above. Accordingly, we expect that we will need to raise additional funds in the future. In connection with our initial public offering, we agreed not to issue additional shares of our common stock without our underwriters' consent, which such consent has been obtained. As such, we may conduct additional offerings of our common stock or common stock equivalents in the future.

We may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us

Our financial condition would be adversely impacted if our intangible assets become impaired.

As a result of the accounting for our acquisition of Moleculin, LLC and the agreement we entered into with Houston Pharmaceuticals, Inc., we have carried on our balance sheet within intangible assets in-process research and development ("IPR&D") of \$11,128,790 as of September 30, 2016. Intangibles are tested for impairment at least annually or when events or changes in circumstances indicate the carrying value of each segment, and collectively our company taken as a whole, might exceed its fair value. We have retained a third party valuation firm to provide us with an initial valuation of these intangible assets; and we expect to receive their final report during the fourth quarter of 2016.

Intangible assets related to IPR&D are considered indefinite-lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. 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, the IPR&D assets will be amortized over their estimated useful lives.

If after receipt of the foregoing valuation report we determine that the value of our intangible assets is less than the amounts reflected on our balance sheet, we will be required to reflect an impairment of our intangible assets in the period in which such determination is made. An impairment of our intangible assets would result in our recognizing an expense in the amount of the impairment in the relevant period, which would also result in the reduction of our intangible assets and a corresponding reduction in our stockholders' equity in the relevant period. As the transactions discussed above were related party transactions and were not conducted on an arm's length basis, it is possible that the terms were less favorable to us than what we would have received in an arm's length transaction. We can provide no assurance that the final valuation of our intangible assets will not result in an impairment charge.

Failure to maintain effective internal control over our financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could cause our financial reports to be inaccurate

We are required pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, to maintain internal control over financial reporting and to assess and report on the effectiveness of those controls. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our management concluded that our disclosure controls and procedures were, and continue to be, ineffective as of June 30, 2016, and identified a material weakness in our internal controls over the accounting and reporting for acquisitions. While management is working to remediate the material weakness, there is no assurance that the changes will remediate the identified material weakness or that the controls will prevent or detect future material weaknesses. If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business.

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

(a) On various dates from August 31, 2015 through January 19, 2016, each as amended on March 10, 2016, we issued certain 8% unsecured promissory notes in aggregate principal amount of \$615,000 to certain accredited investors. Upon the completion of the IPO, these notes provided that they be automatically converted into shares of our common stock at their applicable conversion prices, which were \$0.1299 with respect to \$250,000 in notes and \$0.20 per share with respect to the remaining \$365,000, to the extent and provided that no holder of these notes was or will be permitted to convert such notes to the extent that the holder or any of its affiliates would beneficially own in excess of 4.99% of our common stock after such conversion. Due to this 4.99% limitation, the remaining principal and accrued interest amounts of the effected notes will remain outstanding and will be converted into shares of our common stock at such time as the 4.99% limitation continues to be met. The IPO was completed on May 31, 2016. On May 31, 2016, pursuant to the conversion feature of the foregoing notes and with restriction of the 4.99% beneficially owned condition limitation, we issued 1,166,503 common shares in total, reducing convertible debt principal by \$183,356 and accrued interest by \$17,699. During the three months ended September 30, 2016, an additional 800,057 common shares were issued due to the number of common shares outstanding allowing for conversion of additional shares under the 4.99% beneficially owned condition limitation. This reduced the convertible debt principal by \$133,988 and accrued interest by \$6,742. The remaining convertible debt without consideration of accrued interest as of September 30, 2016, if converted on September 30, 2016, would result in an additional 1,928,899 common shares to be issued. See Note 3 of our financial statements for more information regarding the issuance of the notes.

We believe that the issuances were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering.

(b) On May 31, 2016, we completed our initial public offering, which commenced on May 2, 2016, pursuant to which we sold 1,540,026 shares of our common stock at \$6.00 per share with gross proceeds of \$9,240,156 and net proceeds of \$8,464,183 after deducting underwriting discounts and commissions and offering expenses payable by us. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-209323), which was declared effective by the SEC on May 2, 2016. Bonwick Capital Partners LLC and Network 1 Financial Securities, Inc. acted as underwriters for the offering.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on May 3, 2016 pursuant to Rule 424(b). No direct or indirect payments were made by us to any of our directors or officers or their associates, to persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and those payments disclosed above with regard to the license arrangements with HPI. Pending the uses described, we intend to invest the net proceeds in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Title of Document
10.1	Employment Agreement between Moleculin Biotech, Inc. and Jonathan P. Foster dated August 19, 2016 (incorporated by reference to Exhibit 10.1 of the Form 8-K filed August 25, 2016)**
10.2	Executive Employment Agreement between Moleculin Biotech, Inc. and Walter Klemp dated October 13, 2016 (incorporated by reference to Exhibit 10.1 of the Form 8-K filed October 13, 2016)**
10.3	General Release and Separation Agreement between Moleculin Biotech, Inc. and Louis Ploth dated October 7, 2016 (incorporated by reference to Exhibit 10.2 of the Form 8-K filed October 13, 2016)**
10.4*	Development Collaboration Agreement between Moleculin Biotech, Inc. and Dermin Sp. Z o. o. dated September 30, 2016
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1*(1)	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*(1)	Certification of the Principal Financial Officer pursuant to 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.

** Exhibit is a management contract or compensatory plan or arrangement.

(1) The certifications on Exhibit 32 hereto are deemed not "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

Pursuant to the requirements 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 21, 2016

By: /s/ Walter Klemp
Walter Klemp
Chairman and Chief Executive Officer

Date: November 21, 2016

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

This **DEVELOPMENT COLLABORATION Agreement** (the "**Agreement**") dated as of September 30, 2016 (the "**Effective Date**") is entered into by and between Moleculin Biotech, Inc. ("**MBI**"), a Delaware corporation, having a business address of 2575 West Bellfort Dr., Suite 333, Houston, TX 77054 and Dennin Sp. z o. o. a limited liability company having a principal place of business located at PL-00-116 Warszawa, ul. Switokrzyska 30/63, Poland ("**Dermin**"). **MBI and Dermin** are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, **Dermin** and **AnnaMed** have entered into an Original License Agreement, and;

WHEREAS, **MBI** acquired from **AnnaMed** all the rights and responsibilities of the Original License Agreement, and;

WHEREAS, **Dermin** has rights to Annamycin API and Annamycin DP currently held at Symbiosis Facilities, and;

WHEREAS, **Dermin** now wishes to engage **MBI** manage the use of Annamycin API and Annamycin DP in order to conduct human Clinical Trials, and;

WHEREAS, consistent with the Original License Agreement, the Parties wish to share rights to any and all Development Data that may result from human Clinical Trials;

NOW, THEREFORE, in consideration of the covenants, conditions and agreements hereinafter set forth, and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, **MBI and Dermin** hereby agree as follows:

ARTICLE 1 DEFINITIONS

1.1 "**Affiliate**" means with respect to a Party, any entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Party. For purposes of this definition, "control" of a business entity means the direct or indirect ownership of at least fifty (50%) ownership interests in such entity.

1.2 "**Annamed**" means Annamed, Inc, a former Texas corporation which has since merged with and into MBI.

1.3 "**Annamycin**" means the drug named Annamycin in the Original License Agreement.

1.4 "**Annamycin API**" means the Annamycin active pharmaceutical ingredient.

1.5 "**Annamycin DP**" means Annamycin API converted into a finished drug product for use in humans.

1.6 "Assignment" means the Assignment of the Original License Agreement dated April 20 , 2016, pursuant to which MBI assumed all of the rights, obligations and covenants of Annamed under the Original License Agreement.

1.7 "Clinical Trials" means any investigation in human subjects intended to discover or verify the clinical, pharmacological , and/or other pharmacodynamic effects of Licensed Product, and/or to identify any adverse reactions to Licensed Product, and/or to study absorption, distribution, metabolism, and excretion of Licensed Drug Product with the object of ascertaining its safety and/or efficacy for purposes of obtaining regulatory approval to commercialize and market the Licensed Drug Product.

1.8 "Commercially Reasonable Efforts" means, with respect to the applicable goal or objective hereunder, the efforts, consistent with the practice of comparable pharmaceutical development companies with respect to a comparable pharmaceutical product owned by it or to which it has rights of comparable market potential at a similar stage in its product life (taking into account the competitiveness of the marketplace, the proprietary position of the applicable active ingredient, the regulatory structure involved), that a reasonable person in the position of the obligor would use so as to achieve that goal or objective as expeditiously as possible.

1.9 "Development Data" shall be any data, information or know-how resulting from Clinical Trials in humans, whether conducted by either **MBI or Dermin** using Dermin ' s Annamycin DP.

1.10 "Governmental Authority " means within the Licensed Territory any (i) federal, state or local government; (ii) court, arbitral or other tribunal or governmental or quasi governmental authority of any nature (including any governmental agency, political subdivision, instrumentality, branch department, official, or entity); or (iii) body exercising , or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power of any nature pertaining to government.

1.11 "New Intellectual Property" means new patentable subject matter relating to Annamycin (including but not limited to that which may result from the use of the activities undertaken pursuant to this Agreement), which is not already covered by the Original License Agreement.

1.12 "Laws" means all applicable laws, rules, regulations, judgments, orders, subpoenas, decrees, statutes, ordinances and other requirements of any Governmental Authority or instrumentality within the Licensed Territory.

1.13 "**MBI**" is as defined in the Header of this Agreement.

1.14 "New Intellectual Property" means patent or technology rights developed by MBI relating to the composition of matter, formulation, delivery and use of Annamycin.

1.15 "Original License Agreement" means the Patent and Technology Development and License Agreement dated June 28, 2012 by and between **Annamed** and **Dermin**, which agreement has been assigned by **Annamed to MBI** pursuant to the Assignment.

1.16 "Symbiosis" means Symbiosis Pharmaceutical Services, company existing under the Laws of Scotland, having an address at Stirling Innovation Park, Stirling, FK9 4NF, Scotland, UK.

1.17 "Symbiosis Facilities" means any facility holding Dermin's supply of Annamycin API and Annamycin DP in the custody of Symbiosis.

1.18 "Term" us as defined in Section 5.1 of this Agreement.

ARTICLE 2 ENGAGEMENT

2.1 Subject to the terms and conditions of this Agreement, Dermin and MBI hereby mutually agree that MBI shall manage the conversion of existing Annamycin API into Annamycin DP and the use of Annamycin DP in Clinical Trials in humans.

2.2 Subject to the terms and conditions of this Agreement and consistent with the Original License Agreement, the Parties hereby agree that Development Data shall be shared upon advanced written notice of the requesting Party.

ARTICLE 3 DEVELOPMENT OBLIGATIONS

3.1 MBI shall be solely responsible for any and all costs and expenses related to the exercise of its rights under Article 2 of this Agreement, including, without limitation, any and all costs and expenses associated with the conversion of the Annamycin API into Annamycin DP and the development and design of and conducting Clinical Trials.

3.2 MBI hereby agrees to use Commercially Reasonable Efforts to develop, design and conduct Clinical Trials of Annamycin DP with the intent to obtain regulatory approval under applicable Laws to commercialize and market Annamycin in the United States and Europe.

3.3 Dennin hereby agrees to contract Davos Pharma to convert Annamycin API into Annamycin DP in a manner consistent with the arrangements and procedures currently established between Dennin and Davos Pharma and to direct Davos Pharma to provide Annamycin for use in Clinical Trials as directed by MBI.

ARTICLE 4 DATA AND INTELLECTUAL PROPERTY

4.1 Any and all data generated from the use of Annamycin API and Annamycin DP by a Party shall be the property of that Party, provided however, the other Party shall have the right to use such data subject to the confidentiality provisions set forth in Article 7 of this Agreement.

4.2 Any New Intellectual Property shall be the property of MBI, provided however, that Dermin shall have an option to license New Intellectual Property under the terms and conditions set forth in the Original License Agreement. Dermin shall exercise its option under this Section 4.2 by written notice to MBI.

**ARTICLE 5
TERMINATION**

5.1 This Agreement will become effective as of the Effective Date and will continue until 7 years, unless this Agreement is terminated earlier pursuant to this Article 4 (the "Term").

5.2 If either Party is in material breach of any of its obligations contained in this Agreement, the other Party, if it is not also in material breach hereunder, will be entitled to give to the Party in material breach written notice specifying the nature of such breach and requiring it to cure such breach, to the extent such breach is curable. If such breach is not cured within sixty (60) Business Days after the receipt of such notice, or at the time of such notice is delivered if such breach is not curable, the notifying Party will be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it at law or in equity, to terminate this Agreement by giving written notice, to take effect immediately upon delivery of such notice.

5.3 This Agreement may be terminated, prior to the expiration of the Term, immediately by either Party upon written notice to the other Party in the event that the other Party hereto (i) applies for, consents to, becomes the subject of the appointment of, or the taking of possession by a receiver, custodian, trustee or liquidator of itself or of all or a substantial part of its property; (ii) makes a general assignment for the benefit of its creditors; (iii) commences a voluntary case under the bankruptcy code of the applicable Laws in which it is organized; or (iv) becomes the subject of an involuntary case under the applicable Laws or similar insolvency proceeding, which case or proceeding has not been dismissed or otherwise stayed within ninety (90) days.

5.4 Termination of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of either Party prior to such termination, and such termination will not relive either Party from obligations which are expressly indicated to survive termination of this Agreement.

5.5 Expiration or termination of this Agreement will not relive the Parties of any obligation accruing prior to such expiration or termination. Article 1 (Definitions); Article 2 (Rights); Article 4 (Termination); Article 5 (Representations, Warranties and Covenants); Article 6 (Confidentiality); and Article 7 (Miscellaneous) shall survive expiration of the Term or termination of this Agreement.

**ARTICLE 6
REPRESENTATIONS, WARRANTIES AND COVENANTS**

6.1 Each Party represents and warrants to the other Party that as of the Effective Date:

6.1.1 Each Party is organized and validly existing under the laws of its state of formation.

6.1.2 Each Party has all requisite corporate or company power and authority to execute and deliver this Agreement and to perform all of its obligations hereunder. The execution and delivery of this Agreement and the performance by the Parties of their respective obligations hereunder have been authorized by all requisite corporate or company action, as applicable, on their respective parts. Each Party shall be liable for (i) any breach of this Agreement by any of its Affiliates and (ii) any failure by such Party to cause its Affiliate to comply with this Agreement as if they were parties.

6.2 Dermin represents and warrants to MBI that as of the Effective Date:

6.2.1 Dennin owns and possess all rights, title and interest in, to the Annamycin API and existing Annamycin DP;

6.2.2 Neither the execution and delivery of this Agreement nor the performance of Dermin' s obligations under this Agreement will conflict in any material respect with or result in a material breach of, or constitute a material default under, any contract, agreement or instrument to which Dennin is bound;

6.3 EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT NEITHER PARTY NOR THEIR AFFILIATES MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 7 CONFIDENTIALITY

7.1 MBI and Dermin each agree that Confidential Information of the other Party (i) shall be received in strict confidence, (ii) shall be used only for the purposes of this Agreement, and (iii) will not be disclosed by the Receiving Party (except as required by law, court order or regulation), its agents or employees without the prior written consent of the Disclosing Party

7.2 Subject to full compliance with this Article 7, each Party may disclose the other party' s Confidential Information in confidence to its employees, consultants, Affiliates and potential or actual, investors or other commercial partners, research collaborators and in connection with the performance of its obligations and the exercise of its rights under this Agreement and the procurement of grant funding; provided, however, that (i) the Receiving Party first advises recipients of such disclosure of the confidential nature thereof and (ii) Receiving Party shall be responsible for any breaches of this Agreement by any of such disclosure. Notwithstanding the foregoing, the Receiving Party shall not disclose any Confidential Information of the Disclosing Party to any Third Party who does not have a need to know such Confidential Information.

7.3 Each party's obligation of confidence hereunder will be fulfilled by using at least the same degree of care with the disclosing party's Confidential Information as it uses to protect its own confidential information, but always at least a reasonable degree of care.

7.4 Except as otherwise set forth in this Agreement, the Receiving Party will promptly return all of the Disclosing Party's Confidential Information, including all reproductions and copies thereof in any medium, except that the Receiving Party may retain a single archival copy as may be required by applicable Laws or its standard procedures.

ARTICLE 8 MISCELLANEOUS

8.1 The Parties shall execute and deliver any and all additional papers, documents, and other instruments and shall do any and all further acts and things reasonably necessary, if any, in connection with the performance of its obligation hereunder to carry out the intent of this Agreement.

8.2 This Agreement contains the entire understanding of the Parties. This Agreement may be amended only by a written instrument signed by the Parties.

8.3 In the event an ambiguity or question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise in favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement.

8.4 The waiver by any Party of any terms or condition of this Agreement, or any part hereof, shall not be deemed a waiver of any other term or condition of this Termination Agreement, or of any later breach of this Agreement.

8.5 Any notice required by this Agreement will be given by personal delivery (including delivery by reputable messenger services such as Federal Express) or by prepaid, first class, certified mail, return receipt requested, addressed to:

If to Dermin:

Dermin Sp. z o. o.
Attention: Prezes Zarzadu
PL-00-116 Warszawa,
ul. Swietokrzyska 30/63,
Poland

If to MBI:

Moleculin Biotech, Inc.
Attention: CEO
2575 West Bellfort Dr., Suite 333
Houston, TX 77054
USA

8.6 The Article and Section captions in this Agreement have been inserted as a matter of convenience and are not part of this Termination Agreement.

8.7 This Agreement may be executed in counterparts, all of which together shall constitute a single agreement.

8.8 This Agreement will be governed by, construed and enforced in accordance with the laws of the State of Texas, United States.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement by their duly authorized representatives with full right, power and authority to enter into and perform under this Agreement.

Moleculin Biotech, Inc..

Dennin Sp. z o. o.

By /s/ Walter Klempe
[Printed Name and title]

By /s/ JERZY REPETA
PRESIDENT.
[Printed Name]

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

I, Walter 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 21, 2016

By: /s/ Walter Klemp

Walter Klemp

Chief Executive Officer

**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 21, 2016

By: /s/ Jonathan P. Foster

Jonathan P. Foster

Executive VP & Chief Financial Officer

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 fiscal quarter ended September 30, 2016 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Walter Klemp, Acting 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 21, 2016

By: /s/ Walter Klemp

Walter Klemp

Chief 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.

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 fiscal quarter ended September 30, 2016 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan P. Foster, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 21, 2016

By: /s/ Jonathan P. Foster

Jonathan P. Foster

Executive VP & Chief Financial 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.
