

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended **September 30, 2017**

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_



**MOLECULIN BIOTECH, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**47-4671997**  
(IRS Employer  
Identification Number)

**2575 West Bellfort, Suite 333**  
**Houston, TX**  
(Address of principal executive offices)

**77054**  
(Zip Code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted to its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Registration S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

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

The registrant had 21,136,059 shares of common stock outstanding at November 1, 2017.

**Moleculin Biotech, Inc.**  
**Form 10-Q**  
**For the quarterly period ended September 30, 2017**

**Table of Contents**

<b><u>PART I – FINANCIAL INFORMATION</u></b>	
<b><u>ITEM 1. FINANCIAL STATEMENTS</u></b>	<b><u>3</u></b>
<b><u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	<b><u>20</u></b>
<b><u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u></b>	<b><u>29</u></b>
<b><u>ITEM 4. CONTROLS AND PROCEDURES</u></b>	<b><u>30</u></b>
<b><u>PART II – OTHER INFORMATION</u></b>	<b><u>30</u></b>
<b><u>ITEM 1. LEGAL PROCEEDINGS</u></b>	<b><u>30</u></b>
<b><u>ITEM 1A. RISK FACTORS</u></b>	<b><u>30</u></b>
<b><u>ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u></b>	<b><u>30</u></b>
<b><u>ITEM 3. DEFAULTS UPON SENIOR SECURITIES</u></b>	<b><u>31</u></b>
<b><u>ITEM 4. MINE SAFETY DISCLOSURES</u></b>	<b><u>31</u></b>
<b><u>ITEM 5. OTHER INFORMATION</u></b>	<b><u>31</u></b>
<b><u>ITEM 6. EXHIBITS</u></b>	<b><u>32</u></b>
<b><u>SIGNATURES</u></b>	<b><u>33</u></b>

**PART 1. FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**Moleculin Biotech, Inc.**

**Balance Sheets**

(in thousands except for par and share amounts)

	<u>September 30, 2017</u>	<u>December 31, 2016</u>
	<u>(Unaudited)</u>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,736	\$ 5,007
Prepaid expenses and other	727	215
<b>Total current assets</b>	<b>9,463</b>	<b>5,222</b>
Furniture and equipment, net of accumulated depreciation of \$14 and \$6, respectively	22	23
Intangible assets	11,148	11,148
<b>Total assets</b>	<b>\$ 20,633</b>	<b>\$ 16,393</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,089	\$ 1,069
Convertible notes payable	—	276
Warranty liability	743	—
<b>Total current liabilities</b>	<b>1,832</b>	<b>1,345</b>
Long-term deferred compensation – related party	150	88
<b>Total liabilities</b>	<b>1,982</b>	<b>1,433</b>
Commitments and contingencies (Note 7)	—	—
Stockholders' equity		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 75,000,000 shares authorized, 20,822,214 issued outstanding at September 30, 2017 and 12,164,852 issued and outstanding at December 31, 2016	21	12
Additional paid-in capital	29,925	19,623
Accumulated deficit	(11,295)	(4,675)
<b>Total stockholders' equity</b>	<b>18,651</b>	<b>14,960</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 20,633</b>	<b>\$ 16,393</b>

See accompanying notes to the financial statements.

**Moleculin Biotech, Inc.**  
**Statements of Operations**  
**(Unaudited)**

(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	1,061	497	2,260	616
General and administrative	1,338	924	2,987	1,848
Depreciation	5	1	13	2
Total operating expenses	<u>2,404</u>	<u>1,422</u>	<u>5,260</u>	<u>2,466</u>
Loss from operations	<u>(2,404)</u>	<u>(1,422)</u>	<u>(5,260)</u>	<u>(2,466)</u>
Other income (expense):				
Loss from change in fair value of warrant liability	(470)	—	(2,753)	—
Gain from settlement of liability	—	—	149	—
Gain from expiration of warrants	—	—	1,238	—
Other income	9	—	8	—
Interest expense	<u>(1)</u>	<u>(10)</u>	<u>(2)</u>	<u>(37)</u>
Net loss	<u>\$ (2,866)</u>	<u>\$ (1,432)</u>	<u>\$ (6,620)</u>	<u>\$ (2,503)</u>
Net loss per common share – basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.12)</u>	<u>\$ (0.37)</u>	<u>\$ (0.28)</u>
Weighted average common shares outstanding – basic and diluted	<u>20,534,720</u>	<u>11,579,239</u>	<u>17,683,441</u>	<u>9,066,804</u>

See accompanying notes to the financial statements.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2017</b>	<b>2016</b>
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (6,620)	\$ (2,503)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation	13	2
Stock-based compensation	487	209
Deferred CEO compensation	62	88
Change in fair value of warrant liability	2,753	—
Gain in settlement of liability	(149)	—
Gain from expiration of warrants	(1,238)	—
Other	(9)	—
<b>Changes in operating assets and liabilities:</b>		
Prepaid expenses	(518)	(245)
Accounts payable and accrued expenses	285	(147)
<b>Net Cash Used in Operating Activities</b>	<b>(4,934)</b>	<b>(2,596)</b>
<b>Cash Flows from Investing Activities:</b>		
Purchase of fixed assets	(12)	(10)
Purchase paid for acquisition of Moleculin, LLC, net with cash acquired	—	(100)
<b>Net Cash Used in Investing Activities</b>	<b>(12)</b>	<b>(110)</b>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from notes payable	—	165
Payments on note payable	—	(470)
Proceeds from exercise of warrants	3,808	—
Proceeds from sale of common stock units, net of cash stock issuance costs	4,867	9,167
<b>Net Cash Provided by Financing Activities</b>	<b>8,675</b>	<b>8,862</b>
<b>Net change in cash and cash equivalents</b>	<b>3,729</b>	<b>6,156</b>
Cash and cash equivalents, at beginning of period	5,007	28
<b>Cash and cash equivalents, at end of period</b>	<b>\$ 8,736</b>	<b>\$ 6,184</b>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid for interest	\$ 2	\$ 48
Cash paid for income taxes	\$ —	\$ —
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Common stock issued for conversion of debt	\$ 302	\$ 342
Common stock issued for services provided	\$ 89	\$ —
Common stock issued to acquire Moleculin, LLC	\$ —	\$ 9,774

See accompanying notes to the financial statements.

**Moleculin Biotech, Inc.**  
**Statements of Stockholders' Equity**  
**(Unaudited)**  
(in thousands except for shares and per unit)

	<u>Common Stock</u>		<b>Additional Paid-In- Capital</b>	<b>Accumulated Deficit</b>	<b>Stockholders' Equity</b>
	<b>Number</b>	<b>Amount</b>			
Balance at December 31, 2016	12,164,852	\$ 12	\$ 19,623	\$ (4,675)	\$ 14,960
Issued for cash – sale of units at \$1.35 per unit, net of stock issuance costs of \$550	3,710,000	4	313		317
Warrants exercised, net of issuance costs of \$80	2,703,434	3	8,753		8,756
Issued for cash - sale of common stock in ATM offering, net of issuance costs of \$47	154,121	—	360		360
Stock-based compensation			487		487
Issued for convertible debt	2,010,640	2	300		302
Issued for settlement of service	79,167	—	89		89
Net loss				(6,620)	(6,620)
Balance at September 30, 2017	<u>20,822,214</u>	<u>\$ 21</u>	<u>\$ 29,925</u>	<u>\$ (11,295)</u>	<u>\$ 18,651</u>

See accompanying notes to the financial statements.

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

**1. Nature of Business and Liquidity**

The terms “MBI” or the “Company”, “we”, “our” and “us” are used herein to refer to Moleculin Biotech, Inc. MBI is a clinical stage pharmaceutical company organized as a Delaware corporation in July 2015 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.

We currently have four drug candidates representing three substantially different approaches to treating cancer. Liposomal Annamycin, which we refer to as Annamycin, is a chemotherapy designed to inhibit the replication of DNA of rapidly dividing cells. WP1122 is an inhibitor of glycolysis intended to cut off the fuel supply of tumor cells, which are often overly dependent on glycolysis as compared to healthy cells. And, finally, WP1066 and WP1220, have shown capability, in *in vivo* testing, of altering the cell signaling associated with tumors.

Annamycin is an anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML. In August 2015, the Company acquired the rights and prior development data regarding Annamycin and the prior Annamycin investigational new drug application (“IND”) with the U.S. Food and Drug Administration (“FDA”), including all trade secrets, know-how, confidential information and other intellectual property rights. Annamycin had been in clinical trials pursuant to an IND filed with the FDA by a prior drug developer, which was terminated when that developer ceased activity for financial reasons. Our review of that prior clinical data leads us to believe that Annamycin may have greater potential for efficacy and safety in relapsed or refractory AML patients than currently available therapies.

Because the prior developer of Annamycin allowed their IND to lapse, we were required to submit a new IND for continued clinical trials with Annamycin, which the FDA was allowed to proceed on September 22, 2017. The Company announced on October 3, 2017 that it had signed an agreement with a hospital in Poland to participate in this trial, which will be our first clinical site, assuming the receipt of regulatory approval in Poland. The data presented in our successful IND submission to FDA were submitted to Polish regulatory authorities on October 23, 2017, in support of our request for Clinical Trial Authorization (“CTA”) in that country. Depending on the timing of the CTA approval, we could begin treating patients in a Phase I/II clinical trial, as early as late December of 2017. The Phase I dose-ranging portion of this trial is designed to establish a new Recommended Phase 2 Dosage, or RP2D, which we believe was not adequately explored in previous trials.

The Annamycin drug substance is no longer covered by any existing patent protection. On July 18, 2017, the Company announced that it had signed a new technology license agreement with MD Anderson Cancer Center based on new patent applications that the Company intends to file relating to Annamycin. These patent applications are related to the 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.

On March 21, 2017, we received notice that the FDA had granted us Orphan Drug designation for Annamycin for the treatment of AML. Orphan Drug status could entitle us to market exclusivity of up to 7 and 10 years from the date of approval of a New Drug Application (“NDA”) in the United States. If we obtain similar designation in the European Union (“EU”), we could be entitled to 10 years of market exclusivity there from the date of approval of a Marketing Authorization Application (“MAA”) in the United States and the European Union (“EU”), respectively. Separately, the FDA may also grant market exclusivity of up to 5 years with the approval of an active moiety (a “new chemical entity,” which we anticipate Annamycin would be), but there can be no assurance that such exclusivity will be granted.

Our other drug development projects relate to two distinct portfolios 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) and pancreatic cancer 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.

During 2017, the Company announced the following progress on these two portfolios: 1) that it engaged a contract research organization (“CRO”) to prepare for a proof-of-concept trial in Poland to study the Company's drug candidate WP1220 (part of the WP1066 portfolio described above) for the treatment of cutaneous T-cell lymphoma; 2) the Company entered into collaborative agreements with the University of Bergen in Norway to test WP1122 in combination with another drug in the treatment

of brain tumors and separately to conduct further analysis on the capability of WP1066 to stimulate anti-tumor immune response: 3) the Company entered into an agreement with the Mayo Clinic to study WP1066 for the treatment of rare pediatric brain tumors: and 4) the Company agreed to assist MD Anderson in submitting an IND for the study of WP1066 in glioblastoma and melanoma that has metastasized to the brain, which MD Anderson filed on November 1, 2017.

In accordance with FASB ASC Topic 280, Segment Reporting, we view our operations and manage our business as principally one segment. As a result, the financial information disclosed herein represents all the material financial information related to our principal operating segment.

## 2. Summary of Significant Accounting Policies

**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 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 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, 2016 and for the period from July 28, 2015 (inception) to December 31, 2015 and notes thereto contained in the Form 10-K filed with the SEC on April 3, 2017.

**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.

**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 ability of the Company to obtain necessary equity financing to continue operations and the attainment of profitable operations. As of September 30, 2017, the Company has incurred an accumulated deficit of \$11.3 million since inception, and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of September 30, 2017 is sufficient to fund its planned operations into but not beyond the near term. These factors raise substantial doubt regarding the Company’s ability to continue as a going concern. These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements and delay planned cash outlays or a combination thereof. Management cannot be certain that such events or a combination thereof can be achieved.

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

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

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

Level 1 – Unadjusted quoted prices in active markets of identical assets or liabilities.

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

Level 3 – Unobservable inputs for the asset or liability.

The Company’s financial assets and liabilities recorded at fair value on a recurring basis include the fair value of our warrant liability discussed in Note 4. The fair value of this warrant liability is included in current liabilities on the accompanying financial statements as of September 30, 2017, as warrants are currently being exercised.

The following table provides the financial assets and liabilities reported at fair value and measured on a recurring basis at September 30, 2017:

*In thousands*

Description	Liabilities Measured at Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Fair value of warrant liability:				
2017	\$ 743	\$ —	\$ —	\$ 743

The following table provides a summary of changes in fair value associated with the Level 3 liabilities for the quarter ended September 30, 2017:

*In thousands*

	Warrant Liability – Current	Warrant Liability – Long-Term	Warrant Liability – Total
Balance, June 30, 2017	\$ 1,185	\$ —	\$ 1,185
Reclass of liability from long-term to current	—	—	—
Change in fair value - net	470	—	470
Expiration of warrants	—	—	—
Transfer in and out (exercise of warrants)	(912)	—	(912)
Balance, September 30, 2017	\$ 743	\$ —	\$ 743

The following table provides a summary of changes in fair value associated with the Level 3 liabilities for the nine months ended September 30, 2017:

*In thousands*

	Warrant Liability – Current	Warrant Liability – Long-Term	Warrant Liability – Total
Balance, beginning of period December 31, 2016	\$ —	\$ —	\$ —
Issuances of warrants	2,453	1,690	4,143
Reclass of liability from long-term to current	1,846	(1,846)	—
Change in fair value - net	2,848	(95)	2,753
Transfers in and out (exercise of warrants)	(5,166)	251	(4,915)
Expiration of warrants	(1,238)	—	(1,238)
Balance, September 30, 2017	\$ 743	\$ —	\$ 743

The above table of Level 3 liabilities begins with the initial valuation given the issuances occurred in the first quarter of 2017 and adjusts the balances for changes that occurred during the current quarter and prior quarter. The ending balance of the Level 3 financial instrument presented above represent our best estimates and may not be substantiated by comparison to independent markets and, in many cases, could not be realized in immediate settlement of the instruments.

**Loss Per Common Share** - Basic net loss per common share is computed by dividing net loss available to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is determined using the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents. In periods when losses are reported, the weighted-average number of common shares outstanding excludes common stock equivalents, because their inclusion would be anti-dilutive. For the three and nine months ended September 30, 2017, the Company's potentially dilutive shares, which were not included in the calculation of net loss per share, included options to purchase 670,000 common shares and warrants to purchase 702,576 common shares as inclusion of these securities would have been anti-dilutive.

**Reclassifications** – A reclassification was made to the December 31, 2016 financial statements to conform to the 2017 presentation. Such reclassification did not affect net loss as previously reported. Historically, accrued interest associated with “convertible notes payable” was included in the line item “accounts payable and accrued expense”. Management believes that these costs are best shown included in the amounts shown for “convertible notes payable” and, as such, a reclassification was made to the balance sheet for the year ended December 31, 2016 by reducing “accounts payable and accrued expenses” and increasing “convertible notes payable” by \$0.02 million.

**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 events disclosure consideration and has noted events in Note 8 below.

### **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 at the time the Company starts to generate revenue or enters into other contractual arrangements, which the Company does not expect in the near term.

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 ending after December 15, 2016, and for annual and interim periods thereafter; early adoption is permitted. This disclosure is effective within these financial statements for the year ended December 31, 2016 and thereafter. Such disclosure did not impact the 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 adoption of this standard on January 1, 2017, did not have a significant impact on the Company's financial statements.

In August 2016, the FASB issued ASU, Statement of Cash Flows (Topic 230). This ASU applies to all entities that are required to present a statement of cash flows under Topic 230. The amendments provide guidance on eight specific cash flow issues and includes clarification on how these items should be classified in the statement of cash flows and is designed to help eliminate diversity in practice as to where items are classified in the cash flow statement. Furthermore, in November 2016, the FASB issued additional guidance on this Topic that requires amounts generally described as restricted cash and restricted cash equivalents to be included with cash and cash equivalents when reconciling the statement of cash flows. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, with earlier application permitted for all entities. We plan to adopt the provisions of this ASU for our fiscal year beginning January 1, 2018 and are currently evaluating the impact the adoption of this new accounting standard will have on our financial statements.

In January 2017, the FASB issued ASU 2017-01 "Business Combinations (Topic 805)," which provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. If the screen is not met, the amendments in this update (1) require that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments in this update also narrow the definition of the term "output" so that the term is consistent with how outputs are described in Topic 606. Public business entities are required to apply the amendments in this update to annual periods beginning after December 15, 2017, including interim periods within those periods. Early application is permitted. The Company will evaluate the effect of the update at the time of any future acquisition or disposal.

In May 2017, the FASB issued ASU 2017-09 "Compensation—Stock Compensation (Topic 718)." This update clarifies the existing definition of the term "modification," which is currently defined as "a change in any of the terms or conditions of a share-based payment award." The update requires entities to account for modifications of share-based payment awards unless the (1) fair value, (2) vesting conditions and (3) classification as an equity instrument or a liability instrument of the modified award are the same as of the original award before modification. Public business entities are required to adopt the amendments in this update for fiscal years and interim periods beginning after December 15, 2017, with early adoption permitted. The Company will adopt the update when it becomes effective. The Company is in the process of determining the impact, if any, this adoption 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.

### **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 bore interest at 8.0% per annum and was to mature on the earlier of September 30, 2016 or the completion of an IPO of the Company's securities.

Since the completion of the IPO occurred prior to September 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 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 remained outstanding and was converted into shares of our common stock at such time as the 4.99% limitation was met. Until such time as the notes were converted into shares of common stock, the maturity date of the notes was automatically extended and we were not 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 \$0.18 million and accrued interest by \$0.02 million. Subsequent to these transactions and through June 30, 2017, an additional 2,920,738 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 \$0.3 million and accrued interest by \$0.03 million.

On June 22, 2017, 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 804,098 common shares in total, which effectively converted all remaining outstanding convertible debt and accrued interest outstanding as of that date. This conversion converted the remaining amount of debt and accrued interest at June 22, 2017 of \$0.1 million.

#### **4. Warrant Liability**

On February 9, 2017, the Company entered into an Underwriting Agreement (the “Underwriting Agreement”) with Roth Capital Partners, LLC, as representative of the several underwriters identified therein (collectively, the “Underwriters”), pursuant to which we sold in a registered public offering (the “Offering”), 3,710,000 units, priced at a public offering price of \$1.35 per unit (the closing price that day was \$1.50), with each unit consisting of: (i) one share of common stock, (ii) a five-year Series A warrant to purchase 0.50 of a share of common stock, (iii) a 90-day Series B warrant to purchase one share of common stock, and (iv) a five-year Series C warrant to purchase 0.50 of a share of common stock. The Series C warrants in a unit could only be exercised to the extent and in proportion to a holder of the Series C warrants exercising its Series B warrants included in the unit. The Series A and Series C warrant have an exercise price of \$1.50 per share of common stock. The Series B warrant had an exercise price of \$1.35 per share of common stock.

Under the terms of the Underwriting Agreement, we granted the Underwriters a 45-day option to purchase an additional 556,500 shares of common stock and/or an additional 556,500 warrant combination (comprised of an aggregate of 278,250 Series A warrants, 556,500 Series B warrants and 278,250 Series C warrants), in any combinations thereof, from us to cover over-allotments at the public offering price per share of \$1.349 and public offering price per warrant combination of \$.001, respectively, less the underwriting discounts and commissions. Upon the closing of the Offering, the Underwriters exercised the over-allotment option with respect to \$278,100 warrant combinations. We received approximately \$4.5 million in net proceeds from the Offering, after deducting underwriting discounts and commissions and estimated offering expenses.

The basis of value is fair value, which is defined pursuant to Accounting Standards Codification (“ASC”) 820 to be “the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date”. The Company estimated the fair value of the Warrants under ASC 820 as of February 14, 2017 for financial reporting purposes. We used the Black-Scholes option pricing model (“BSM”) to determine the fair value of the Series A and Series B Warrants and a Monte Carlo simulation (“MCM”) with regard to the Series C Warrants in consideration of path dependent vesting terms of the contract. Both the BSM and MCM models are acceptable in accordance with GAAP. The BSM requires the use of a number of assumptions including volatility of the stock price, the weighted average risk-free interest rate, and the weighted average term of the Warrant. The MCM simulates the Company’s common stock price from the valuation date through the Series B Warrant and the unvested Series C Warrant expiration dates using Geometric Brownian Motion on a risk-neutral basis – thereby impacting the likelihood that the Series B Warrants would have been exercised and, subsequently, the Series C Warrants would then vest. As disclosed, all Series B and unvested Series C warrants expired on May 15, 2017.

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

Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the expected life of the Warrants. Where appropriate, we used the historical volatility of peer entities due to the lack of sufficient historical data of our stock price during 2016-2017.

The assumptions used in the BSM and MCM models for the Warrants are as follows:

	Nine Months Ended September 30, 2017	Year Ended December 31, 2016
Risk-free interest rate	1.68%-1.86%	—
Volatility	80.00%-160.11%	—
Expected life (years)	0.5-5.0	—
Dividend yield	—%	—

A summary of our Warrant activity and related information follows:

Description	Number of Shares Under Warrant	Range of Warrant Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Balance at January 1, 2017	—	—	—	—
Granted	8,235,923	\$1.35-\$1.50	\$ 1.43	1.6
Exercised	(2,703,434)	—	\$ 1.46	—
Expired	(5,087,717)	—	\$ 1.40	—
Balance at September 30, 2017	444,772	—	\$ 1.46	4.63
Vested and Exercisable at September 30, 2017	444,772	\$1.35-\$1.50	\$ 1.46	4.63

#### Warrant Activity During 2017:

On February 14, 2017, 8,235,923 Warrants were granted, as discussed above.

On March 24, 2017, 596,300 Series B Warrants were exercised for an equivalent amount of common shares which vested 298,150 Series C Warrants.

On March 31, 2017, the Warrants were revalued with a fair value determination of \$3.08 million which included a fair value adjustment of \$1.06 million which was included as a gain from the change in fair value of warrant liability in “Other Income” in the accompanying financial statements.

On May 15, 2017, approximately 3.4 million and 1.7 million Series B and Series C Warrants, respectively, expired, which reduced our warrant liability by \$1.24 million in the accompanying financial statements.

On June 28, 2017, 1,295,995 Series A Warrants were exercised. On the same date, 295,650 Series C Warrants were exercised.

On June 30, 2017, 12,250 Series A Warrants were exercised.

On June 30, 2017, the Warrants were revalued with a fair value determination of \$1.2 million which included a fair value adjustment of \$3.3 million which was included as loss from the change in fair value of warrant liability in “Other income (expense)” in the accompanying financial statements.

During the quarter ended September 30, 2017, 500,739 Series A warrants and 2,500 Series C warrants were exercised with cash proceeds of approximately \$0.8 million.

#### Series B and Series C Warrants

The Series B Warrants and the unvested Series C Warrants expired May 15, 2017. Therefore, the associated warranty liability of \$1.24 million was extinguished on May 15, 2017 as no other Series B Warrants were exercised prior to that date.

## 5. 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, 2017, there was no issued preferred stock.

### Common Stock

On January 13, 2017, the Company agreed to issue 79,167 shares of common stock to a consultant in full settlement for prior services rendered to the Company. Settlement occurred February 21, 2017 with the issuance of the shares, resulting in a gain on settlement of \$0.15 million recorded in gain in settlement of liability on the Statement of Operations. The obligation of \$0.24 million had been recorded by the Company in accounts payable and accrued expenses as of December 31, 2016.

On February 14, 2017, the Company completed a public offering and sold 3,923,923 shares of the Company's common stock. The offering price per unit was \$1.35. The Company received net cash proceeds of \$4.5 million after deducting underwriting discounts, commissions and direct offering expenses payable by us. See Note 4 above regarding Warrant issuances related to our February public offering.

During September 2017, the Company sold 154,121 shares of common stock from \$2.52 to \$2.71 per share with net cash proceeds of \$0.4 million.

### 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, 2017:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2016	510,000	\$ 3.40	\$ 5.28	9.29	\$ 275,500
Granted	160,000	\$ 1.52	\$ 2.14		
Outstanding, September 30, 2017	670,000	\$ 2.12	\$ 1.78	8.85	\$ 144,900
Exercisable, September 30, 2017	85,000	\$ 1.66	\$ 1.79	7.15	\$ 117,300

In January 2017, the Company granted members of its science advisory board options in the aggregate to purchase 20,000 shares of the Company's common stock with an exercise price of \$2.31 per share, a term of 10 years, and a vesting period of 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 \$35,196 that was calculated using the Black-Scholes option-pricing model. In July and August 2017, the Company granted options to the Board and a management member to purchase 140,000 shares of the Company's common stock with exercise

prices of \$1.87 and \$2.88, respectively, with a term of 10 years and a vesting period of 4 years. The options have an aggregated fair value of \$269,592 for the nine months ended September 30, 2017, calculated using the Black-Scholes option-pricing model.

Variables used in the Black-Scholes option-pricing model include ranges of: (1) discount of 1.30%-2.24%, (2) expected lives of 5 to 6.25 years, (3) expected volatility of 70.18% to 89.11%, and (4) zero expected dividends. The Company, due to the limited number of participants in the plan and their positions within the Company, uses a 0% estimated forfeiture rate. For the three and nine months ended September 30, 2017, the Company recorded \$0.2 million and \$0.5 million, respectively in stock-based compensation in relation to the options. As of September 30, 2017, there was \$1.6 million of unrecognized compensation cost, net of estimated forfeitures, related to the Company's non-vested equity awards, which is expected to be recognized over a weighted average period of 3.34 years.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the above paragraph. The expected term of the options was computed using the "plain vanilla" method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin 107 because we do not have sufficient data regarding employee exercise behavior to estimate the expected term. The volatility was determined by referring to the average historical volatility of a peer group of public companies because we do not have sufficient trading history to determine our historical volatility. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

### **GSK Consulting Agreement**

On July 29, 2017, the Company entered into a consulting agreement with GSK Strategies, LLC ("GSK"), for its investor relations operations. The consulting agreement covers for a period of twelve months from the date of July 29, 2017. In exchange for the consulting services, the Company agreed to issue two warrants (collectively, the "Warrants") to purchase 100,000 and 50,000 shares of common stock at exercise prices of \$2.41 and \$3.00 per share, respectively, subject to approval by Nasdaq of a listing of additional shares application, which was received in August 2017.

Each of the Warrants vests over a 12-month period in equal monthly installments starting July 29, 2017, provided that GSK is providing Services to the Company pursuant to the consulting agreement on each vesting date. The Warrants became initially exercisable on August 8, 2017, and expire five years from the initial exercise date. The Company recorded stock compensation expense for the non-employee consulting agreement of \$63,000 for the period ended September 30, 2017 based on the fair value of the warrants vested as of September 30, 2017.

### **At Market Issuance Sales Agreement**

On September 15, 2017, the Company entered into an At Market Issuance Sales Agreement (the "Agreement") with Roth Capital Partners, LLC and National Securities Corporation (collectively, the "Agents"). Pursuant to the terms of the Agreement, the Company may sell from time to time through the Agents shares of the Company's common stock with an aggregate sales price of up to \$13.0 million (the "Shares").

Any sales of Shares pursuant to the Agreement will be made under the Company's effective "shelf" registration statement on Form S-3 (File No. 333-219434) which became effective on August 21, 2017 and the related prospectus supplement and the accompanying prospectus, as filed with the Securities and Exchange Commission (the "SEC") on September 15, 2017. Under the Agreement, the Company may sell Shares through an Agent by any method that is deemed an "at the market offering" as defined in Rule 415 under the Securities Act of 1933, as amended (the "Securities Act").

Sales of the Shares may be made at market prices prevailing at the time of sale, subject to such other terms as may be agreed upon at the time of sale, including a minimum sales price that may be stipulated by the Company's Board of Directors or a duly authorized committee thereof. The Company or the Agents, under certain circumstances and upon notice to the other, may suspend the offering of the Shares under the Agreement. The offering of the Shares pursuant to the Agreement will terminate upon the sale of Shares in an aggregate offering amount equal to \$13.0 million, or sooner if either the Company or the Agents terminate the Agreement pursuant to its terms.

The Company agreed to pay a commission to the Agents of 3.0% of the gross proceeds of the sale of the Shares sold under the Agreement and to reimburse the Agents for certain expenses. The Company has also provided the Agents with customary indemnification rights. The Company is not obligated to make any sales of Common Stock under the Agreement.

As of September 30, 2017, the Company had sold 154,121 shares with gross proceeds of \$0.4 million under this Agreement.

## **6. Income Taxes**

Deferred income tax assets and liabilities are determined based upon differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We do not expect to pay any significant federal or state income tax for 2017 as a result of the losses recorded during the nine months ended September 30, 2017 and the additional losses expected for the remainder of 2017 and net operating loss carry forwards from prior years. Accounting standards require the consideration of a valuation allowance for deferred tax assets if it is “more likely than not” that some component or all of the benefits of deferred tax assets will not be realized. As of September 30, 2017, we maintained a full valuation allowance for all deferred tax assets.

The Company recorded no income tax provision for the nine months ended September 30, 2017 and 2016. The effective tax rate for the nine months ended September 30, 2017 and 2016 was 0%. The income tax rates vary from the federal and state statutory rates primarily due to the valuation allowances on the Company’s deferred tax assets. The Company estimates its annual effective tax rate at the end of each quarterly period. Jurisdictions with a projected loss for the year where no tax benefit can be recognized due to the valuation exclusion could result in a higher or lower effective tax rate during a particular quarter depending on the mix and timing of actual earnings versus annual projections.

## **7. Commitments and Contingencies**

### **WP1122 Portfolio**

The rights and obligations to an April 2012 Patent and Technology License Agreement entered into by and between IntertechBio and MD Anderson (the “IntertechBio Agreement”) have been assigned to MBI. Therefore, MBI has obtained a royalty-bearing, worldwide, exclusive license to intellectual property, including patent rights, related to our WP1122 Portfolio and to our drug product candidate, WP1122. In consideration, MBI must 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. Under the agreement, annual maintenance fees are \$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 assignment, MBI agrees 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.

One-time milestone payments are due as follows: 1) Upon commencement of a Phase II study for a licensed product - \$200,000; 2) Upon commencement of a Phase III study for a licensed product - \$250,000; 3) Upon filing of a New Drug Application (“NDA”) for a licensed product - \$400,000; and 4) Upon receipt of market approval for sale of a licensed product - \$500,000. The rights we have obtained pursuant to the assignment of the IntertechBio 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.

### **WP1066 Portfolio**

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

government. The agreement, as amended, has the following the milestone payments: (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.

MBI entered into an out-licensing agreement with Houston Pharmaceuticals, Inc. (“HPI”), pursuant to which we have granted certain intellectual property rights to HPI, including rights covering the potential drug candidate, WP1066 (“HPI Out-Licensing Agreement”). Under the HPI Out-Licensing Agreement we must make quarterly payments totaling \$0.75 million for the first twelve quarters following the effective date of May 2, 2016, of the HPI Out-Licensing Agreement in consideration for the right to development data related to the development of licensed products. Notwithstanding our obligation to make the foregoing payments, the HPI Out-Licensing Agreement does not obligate HPI to conduct any research or to meet any milestones. Upon payment in the amount of \$1.0 million to HPI within three years of the effective date of the HPI Out-Licensing Agreement we will regain all rights to the licensed subject matter and rights to any and all development data and any regulatory submissions including any IND, NDA or ANDA related to the licensed subject matter and can end the license without any other obligation other than the aforementioned quarterly payments. In the event that we do not exercise our right to regain our rights to the licensed subject matter within three years of the effective date of the HPI Out-Licensing Agreement, the license granted to HPI shall convert to an exclusive license upon HPI’s written notice and we shall be obligated to transfer all existing data relating to licensed subject matter including any development data and any IND to HPI.

On January 9, 2017, the Company amended its Sponsored Laboratory Study Agreement with MD Anderson whereby the Company would pay \$302,500 in 2017, which had been fully paid as of July 31, 2017, and the agreement was extended to October 31, 2018.

### **Annamycin**

As of August 2015, we obtained the rights and obligations of Annamed under a June 2012 Patent and Technology Development and License Agreement by and between Annamed and Dermin (the “Annamed Agreement”). Therefore, certain intellectual property rights, including rights, if any, covering the potential drug product, Annamycin have been licensed to Dermin and Dermin has been granted a royalty-bearing, exclusive license to manufacture, have manufactured, use, import, offer to sell and/or sell products in the field of human therapeutics under the licensed intellectual property in the countries of Poland, Ukraine, Czech Republic, Hungary, Romania, Slovakia, Belarus, Lithuania, Latvia, Estonia, Netherlands, Turkey, Belgium, Switzerland, Austria, Sweden, Greece, Portugal, Norway, Denmark, Ireland, Finland, Luxembourg, Iceland, Kazakhstan, Russian Federation, Uzbekistan, Georgia, Armenia, Azerbaijan and Germany (“Annamed licensed territories”). MBI is obligated to develop and provide a dossier containing data related to the licensed subject matter to Dermin. In consideration, Dermin will pay a royalty for the sale of any licensed product in the Annamed licensed territories and pay all out-of-pocket expenses incurred by MBI in filing, prosecuting and maintaining the licensed patents for which the license has been granted. Dermin also agrees to provide a percentage of certain consideration that Dermin receives pursuant to sublicense agreements.

### **8. Subsequent Events**

Subsequent to September 30, 2017 and through the date of filing of these financial statements, approximately 25,000 additional Series A warrants related to our February 2017 public offering of common stock have been exercised, leaving approximately 420,000 Series A and Broker warrants outstanding. As a result of this exercise, the Company received approximately \$0.04 million.

Additionally, under the At Market Issuance Sales Agreement mentioned in Note 5 and subsequent to September 30, 2017, the Company sold approximately 345,000 shares with gross proceeds of approximately \$0.8 million.

On October 3, 2017, the Board of Directors, after researching comparable companies and using a leading industry survey, approved the issuance of 10-year options, with 4-year vesting, to purchase 590,000 shares, in the aggregate, of the Company’s common stock, under the Company’s 2015 Stock Plan, to its executive officers and other employees. The options had an exercise price of \$2.49 per share.

On October 31, 2017, the Company added Sandra Silberman, M.D., PH.D., as Chief Medical Officer - New Products. The Board of Directors approved the issuance of 10-year options, with 4-year vesting, to purchase 75,000 shares of the Company’s common stock, under the Company’s 2015 Stock Plan to Dr. Silberman. The options had an exercise price of \$1.92 per share.

On November 1, 2017, the Board of Directors approved the issuance of 10-year options, with 4-year vesting, to purchase 10,000 shares, each, of the Company's common stock, under the Company's 2015 Stock Plan to two potential new members of the Science Advisory Board, subject to the approval process of their respective institutions. The options had an exercise price of \$1.95 per share.

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("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.

Forward-looking statements include, but are not limited to, statements about:

- 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;
- Our ability to complete our clinical trials in a timely fashion and within our expected budget;
- Compliance with obligations under intellectual property licenses with third parties;
- Any delays in regulatory review and approval of 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 product candidates;
- 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 clinical-stage pharmaceutical development company organized as a Delaware corporation in July 2015 to focus on the development of anti-cancer drug candidates. We currently have four drug candidates representing three substantially different approaches to treating cancer. Liposomal Annamycin, which we refer to as Annamycin, is a chemotherapy designed to destroy the DNA of rapidly replicating tumor cells. WP1122 is an inhibitor of glycolysis intended to cut off the fuel supply of tumor cells, which are often overly dependent on glycolysis as compared to healthy cells. And, finally, WP1066 and WP1220, have shown capability, in *in vivo* testing, of altering the cell signaling associated with tumors.

Annamycin is an anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML. In August 2015, the Company acquired the rights and prior development data regarding Annamycin and the prior Annamycin investigative new drug application ("IND") with the U.S. Food and Drug Administration ("FDA"), including all trade secrets, know-how, confidential information and other intellectual property rights. Annamycin had been in clinical trials pursuant to an IND filed with the FDA by a prior drug developer, which was terminated when that developer ceased activity for financial reasons. Our review of that prior clinical data leads us to believe that Annamycin may have greater potential for efficacy and safety in relapsed or refractory AML patients than currently available therapies.

Because the prior developer of Annamycin allowed their IND to lapse, we were required to submit a new IND for continued clinical trials with Annamycin, which the FDA allowed to proceed on September 22, 2017. The Company announced on October 3, 2017 that it had signed an agreement with a hospital in Poland to participate in this trial, which will be our first clinical site, assuming the receipt of regulatory approval in Poland. The data presented in our successful IND submission to FDA were submitted to Polish regulatory authorities on October 23, 2017 in support of our request for Clinical Trial Authorization ("CTA") in that country. Depending on the timing of the CTA approval, we could begin treating patients in a Phase I/II clinical trial as early as late December of 2017. The Phase I dose-ranging portion of this trial is designed to establish a new Recommended Phase 2 Dosage, or RP2D, which we believe was not adequately explored in previous trials.

The Annamycin drug substance is no longer covered by any existing patent protection. On July 18, 2017, the Company announced

that it had signed a new technology license agreement with MD Anderson Cancer Center based on new patent applications that the Company intends to file relating to Annamycin. These patent applications are related to the 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.

On March 21, 2017, we received notice that the FDA had granted us Orphan Drug designation for Annamycin for the treatment of AML. Orphan Drug status could entitle us to market exclusivity of up to 7 and 10 years from the date of approval of a New Drug Application (“NDA”) in the United States. If we obtain similar designation in the European Union (“EU”), we could be entitled to 10 years of market exclusivity there from the date of approval of a Marketing Authorization Application (“MAA”), in the United States and the European Union (“EU”), respectively. Separately, the FDA may also grant market exclusivity of up to 5 years with the approval of an active moiety (a “new chemical entity,” which we anticipate Annamycin would be), but there can be no assurance that such exclusivity will be granted.

Our other drug development projects relate to two distinct portfolios 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) and pancreatic cancer 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.

During 2017, the Company announced the following progress on the WP1066 and WP1122 portfolios: 1) that it engaged a contract research organization (“CRO”) to prepare for a proof-of-concept trial in Poland to study the Company’s drug candidate WP1220 (part of the WP1066 portfolio described above) for the treatment of cutaneous T-cell lymphoma, 2) the Company entered into collaborative agreements with the University of Bergen in Norway to test WP1122 in combination with another drug in the treatment of brain tumors and separately to conduct further analysis on the capability of WP1066 to stimulate anti-tumor immune response, 3) the Company entered into an agreement with the Mayo Clinic to study WP1066 for the treatment of rare pediatric brain tumors, and 4) the Company agreed to assist MD Anderson in submitting an IND for the study of WP1066 in glioblastoma and melanoma that has metastasized to the brain, which MD Anderson filed on November 1, 2017.

## 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, on behalf of Moleculin, LLC, we entered into a co-development agreement with Houston Pharmaceuticals, Inc., or HPI, which culminated with the merger of Moleculin, LLC into MBI coincident with our initial public offering allowing us to gain control of the WP1066 Portfolio.

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

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

## Portfolio Status

Below are important milestones for each drug/portfolio of the Company.

### *Annamycin*

- Received Orphan Drug Status for Annamycin - On March 21, 2017, we received notice from the FDA that we had obtained Orphan Drug designation for Annamycin for the treatment of AML effective March 20, 2017.
- Possible Improvement in the Recommended Phase II Dose (“RP2D”) in Upcoming Phase I/IIa Clinical Trial - In reviewing prior data, we determined that the prior developer may not have adequately explored the optimum dosing level for Annamycin in AML patients. Accordingly, we planned our clinical trial to begin with a Phase I to establish the RP2D with a follow-on Phase IIa. We believe this change in strategy will add several months to the timeline for eventual final approval of the drug, however, we believe that this extension of time to complete the trial will not prevent us from publicly announcing some, if not all, of the results from our Phase I/II clinical trial sometime in 2018.
- Received allowance for our IND for Annamycin - On September 26, 2017, we announced that the FDA had allowed the Annamycin IND to go into effect, which allows the Company to move forward with its plans for its Phase I/IIa trial for Annamycin in the treatment of relapsed or refractory AML, both here in the United States and, assuming the receipt of certain additional approvals, in Poland. We anticipate that the IRB (“Institutional Review Board”) approvals and site initiations of various clinical sites participating in our Phase I/II clinical trial of Annamycin should begin occurring later in the fourth quarter of 2017.
- The Company announced its first hospital contract for its Polish Annamycin Clinical Trial - On October 3, 2017, the Company announced that it had signed an agreement with its first hospital in Poland to participate in this trial, subject to Polish regulatory approval to proceed with a clinical trial.
- The Company filed its request for Clinical Trial Authorization (“CTA”) in Poland - On October 23, 2017, the Company filed its CTA in Poland which, if granted, will enable a clinical trial to study Annamycin for the treatment of relapsed or refractory AML in Poland. The CTA process in Poland normally takes 60 days. In Poland, a hospital contract is required prior to filing a CTA.
- Relationship with Dermin - The Company has established relations with a company in a Poland - Dermin Sp. z o. o. (“Dermin”). The Company intends to utilize Dermin’s supply of active pharmaceutical ingredient (“API”) for Annamycin in the upcoming clinical Phase I/II clinical trial. Annamycin was previously licensed to Dermin within a limited region in Europe, enabling Dermin to deploy Polish grant funds toward producing Annamycin. We believe Dermin benefits from a data sharing arrangement giving it access to our clinical data necessary for the allowance of the Company's IND will require

the Company to manufacture, at an estimated cost of \$0.2 million, additional drug product using the Dermin API in early 2018.

#### *WP1066*

- Physician-Sponsored IND - A clinician at MD Anderson has advised us that MD Anderson has submitted to the FDA an IND for a physician-sponsored clinical trial involving WP1066 for the treatment of brain tumors. We are participating in a support role, but have no influence on the design or conduct of the clinical trial, or on the IND process. The clinician indicated that the IND was on hold pending further documentation that the WP1066 to be used in the trial was manufactured in accordance with Good Manufacturing Practice or GMP production of WP1066. The Company, on July 25, 2017, announced its intention to provide support to help the clinician address the issue. MD Anderson re-submitted its IND to the FDA on November 1, 2017, with our assistance. We are hopeful that FDA will permit this IND to go into effect in time to allow the trial to begin in 2017, subject to allowance by the FDA, and will produce useful clinical data in 2018. However, we are not in a position to influence the IND process and we can provide no assurance that such time frame will be achieved.
- Preparing for a study for the treatment of Cutaneous T-cell Lymphoma - The Company announced in September 2017 that it engaged a CRO to prepare for a proof-of-concept trial in Poland to study the Company's drug candidate WP1220 (part of the WP1066 portfolio described above) for the treatment of a form of cutaneous T-cell lymphoma.

#### *WP1122*

- Advancement of Preclinical Testing for Brain Tumors with WP1122 - WP1122 is our unique inhibitor of glucose metabolism, which is thought to be an important driver of glycolytic brain tumor progression and survival. A similar chemical structure to that which turns morphine into heroin has been used to allow WP1122 to successfully cross the blood-brain barrier and increase circulation time as compared to conventional inhibitors of glycolysis. On October 25, 2016, we announced promising initial results of the preclinical toxicology work on WP1122. We believe moving forward with full preclinical toxicology testing is key to our ability to generate a proof of concept in humans. We had previously announced the presentation of preclinical data in July 2016, supporting the potential for using WP1122 as a treatment for glioblastoma.
- Collaborative Agreement - The Company entered into a collaborative agreement in September 2017 with the University of Bergen in Norway to test WP 1122 in combination with another drug in the treatment of brain tumors.

#### **Recent Business Developments**

*Commitment to Supply WP1066 for a potentially grant funded study at the Mayo Clinic* - Physician-scientists at the Mayo Clinic have requested and Moleculin has agreed to supply them with WP1066 for testing in a potential grant-funded clinical trial for children with Diffuse Intrinsic Pontine Gliomas (DIPG), a rare and very aggressive form of brain tumor. Animal studies conducted at this center have suggested that DIPG may be particularly sensitive to the inhibition of the activated form of a cell-signaling protein called STAT3, a primary target of WP1066, and their studies have demonstrated significant anti-tumor activity of WP1066 in DIPG *in vitro* and *in vivo* tumor models.

*Announced the Discovery of a Metabolic Inhibitor with the Potential to Treat Pancreatic Cancer* - The Company announced on June 21, 2017, that it has received attention from the scientific community for its glucose decoy technology (WP1122 Portfolio, Moleculin Presents Preclinical Data of Novel Inhibitor of Glycolysis at 28th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, December 13, 2016) as a potential means to starve tumors to death by exploiting their hyper-dependence on glycolysis for energy production. The Company has identified possible new properties of its compound WP1234, a modification to WP1122. In pre-clinical testing, WP1234 has shown improved drug characteristics when compared with WP1122 and a 20 to 50-fold greater ability to kill pancreatic cancer cell lines when compared with traditional inhibitors of glycolysis. The Company believes this discovery now makes WP1234 a promising drug candidate to be studied for the treatment of pancreatic cancer.

*Moleculin Begins Clinical Testing Site Development Efforts in Poland* - On August 3, 2017, the Company announced it appointed Bioscience SA ("Bioscience"), a Polish contract research organization ("CRO") to begin identifying and preparing clinical testing sites in Poland for its drug Annamycin for the treatment of relapsed or refractory AML. Furthermore, on October 18, 2017, the Company announced that 14 qualified cancer clinics (including sites in both the U.S. and Poland) have requested to participate in its clinical trial.

*Closing of a Follow-On Public Offering* - In February 2017, we completed a public offering of our common stock and warrants, pursuant to which we received \$4.5 million in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. On March 24, 2017, warrants associated with this offering were exercised generating an additional \$0.80 million in net proceeds. During the second quarter of 2017, warrants associated with this offering were exercised generating an additional \$2.4 million. In the third quarter, approximately 500,000 warrants were exercised, generating an additional \$0.7 million bringing the total net proceeds from this offering to above \$3.8 million.

*At Market Issuance Sales Agreement* - On September 15, 2017, the Company entered into an At Market Issuance Sales Agreement (the "Agreement") with Roth Capital Partners, LLC and National Securities Corporation (collectively, the "Agents"). Pursuant to the terms of the Agreement, the Company may sell from time to time through the Agents shares of the Company's common stock with an aggregate sales price of up to \$13.0 million. As of September 30, 2017, the Company had sold 154,121 shares with gross proceeds of \$0.4 million under this Agreement and, additionally, subsequent to September 30, 2017, the Company sold approximately 337,000 shares with gross proceeds of \$0.8 million, bringing the total raised from the Agreement to \$1.2 million in gross proceeds.

*Announced Dr. Sandra Silberman as Chief Medical Officer: New Products* - On October 31st, the Company added Sandra Silberman, M.D., PH.D., as Chief Medical Officer - New Products. The Compensation Committee approved the issuance of 10-year options, with 4-year vesting, to purchase 75,000 shares of the Company's common stock, under the Company's 2015 Stock Plan to Dr. Silberman. The options had an exercise price of \$1.92 per share. Dr. Silberman's role will be in addition to that of Dr. Robert Shepard, Moleculin's Chief Medical Officer - Annamycin. Dr. Silberman's career in clinical development began at Pfizer, Inc., where she oversaw the initiation of Tarceva (TM) clinical trials. She then led the global development of Gleevec® at Novartis. Sandra was the first Vice President and Global Therapeutic Area Head in Oncology at Eisai, a role in which she advanced five original compounds into Phases I through III, gaining the first approval for Eisai's proprietary drug, Halavan®. Subsequently, she served as a senior advisor to a number of biopharmaceutical companies, including Bristol-Myers Squibb, AstraZeneca, Imclone, Roche, and numerous biotech companies as an independent industry consultant. She joined Quintiles in 2009 as the Vice President of Oncology and Global Head of Translational Medicine in the newly formed Innovation division, overseeing drug development and novel technologies for new partnerships with the pharmaceutical and biotechnology industries. Sandra earned her B.A., Sc.M. and Ph.D. from the Johns Hopkins University School of Arts and Sciences, School of Public Health and School of Medicine, respectively. Her major focus of investigation and doctoral thesis was in the burgeoning area of tumor immunology. She received her M.D. from Cornell University Medical College, completing a postdoctoral training and her fellowship in hematology/oncology at the Brigham & Women's and the Dana Farber Cancer Institute in Boston. She continued to do research in tumor immunology with a clinical investigator award from the NIH and became an Instructor in Medicine at Harvard Medical School. She then served as an attending physician at Yale University Hospital. Sandra has continued in clinical practice throughout her career in industry, and is currently an attending physician in the Hematology/Oncology clinic at the Duke VA in Durham, NC.

## Results of Operations

The following table sets forth, for the periods indicated, data derived from our statement of operations:

In thousands

### Moleculin Biotech, Inc. Statements of Operations (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(in thousands, except share and per share amounts)			
Revenues	\$ —	\$ —	\$ —	\$ —
Operating Expenses:				
Research and development	1,061	497	2,260	616
General and administrative	1,338	924	2,987	1,848
Depreciation	5	1	13	2
Total operating expenses	<u>2,404</u>	<u>1,422</u>	<u>5,260</u>	<u>2,466</u>
Loss from operations	<u>(2,404)</u>	<u>(1,422)</u>	<u>(5,260)</u>	<u>(2,466)</u>
Other income (expense):				
Loss from change in fair value of warrant liability	(470)	—	(2,753)	—
Gain from settlement of liability	—	—	149	—
Gain from expiration of warrants	—	—	1,238	—
Other income	9	—	8	—
Interest expense	(1)	(10)	(2)	(37)
Net loss	<u>\$ (2,866)</u>	<u>\$ (1,432)</u>	<u>\$ (6,620)</u>	<u>\$ (2,503)</u>

#### Three Months Ended September 30, 2017 compared to three months ended September 30, 2016

**Research and Development Expense.** Research and development (R&D) expense was \$1.1 million and \$0.5 million for the three months ended September 30, 2017 and 2016, respectively. The increase of approximately \$0.6 million mainly represents an increase of approximately: \$0.1 million related to an increase in R&D associated headcount costs; \$0.1 million for sponsored research and related expenses; and, approximately \$0.4 million associated with developing and testing drug product as we prepared our IND for Annamycin and for the related clinical trials.

**General and Administrative Expense.** General and administrative expense was \$1.3 million and \$0.9 million for the three months ended September 30, 2017 and 2016, respectively. The expense increase of approximately \$0.4 million was mainly attributable to the increase in headcount and associated payroll costs of \$0.2 million; \$0.3 million of stock based compensation; and, approximately \$0.1 million in legal, accounting, consulting, and other professional expenses. This was offset by a reduction in public listing expenses of \$0.2 million.

**Loss from Change in Fair Value of Warrant Liability.** The Company recorded a net loss of \$0.5 million in the third quarter of 2017 for the change in fair value on revaluation of its warrant liability associated with its warrants issued in conjunction with its stock offering in February 2017. The Company is required to revalue certain of its 2017 warrants at the time of each warrant exercise and at the end of each reporting period and reflect in the statement of operations a gain or loss from the change in fair value of the warrant in the period in which the change occurred. We calculate the fair value of the warrants outstanding using the Black-Scholes and Monte Carlo Simulation models. A gain results principally from a decline in the Company's share price during the period and a loss results principally from an increase in the Company's share price.

**Net Loss.** The net loss for the three months ended September 30, 2017 was \$2.9 million which included non-cash income of \$0.5 million related to a gain recognized on the expiration of warrants. The net loss also included additional noncash charges for \$0.5 million for stock based compensation and other stock based expenses.

***Nine Months Ended September 30, 2017 compared to nine months ended September 30, 2016***

**Research and Development Expense.** R&D expense was \$2.3 million and \$0.6 million for the nine months ended September 30, 2017 and 2016, respectively. The increase of approximately \$1.7 million mainly represents an increase of approximately: \$0.3 million related to an increase in R&D headcount and associated payroll costs; \$0.3 million for sponsored research and related expenses; approximately \$0.2 million associated with developing and testing drug product as we prepare for clinical trials; \$0.4 million in clinical trial preparation and \$0.5 million related to travel, legal, consultants, and other research costs associated in preparing our IND and Orphan Drug applications with the FDA.

**General and Administrative Expense.** General and administrative expense was \$3.0 million and \$1.8 million for the nine months ended September 30, 2017 and 2016, respectively. The expense increase of approximately \$1.2 million was mainly attributable to the increase in headcount and associated payroll costs of \$0.5 million; \$0.5 million of stock based compensation; approximately \$0.3 million in legal, accounting, consulting, and other professional expenses; approximately \$0.1 million in insurance expense; and \$0.1 million in travel expenses. These costs were offset by a reduction in public listing expenses of \$0.3 million.

**Loss from Change in Fair Value of Warrant Liability.** The Company recorded a net loss of \$2.8 million in the nine months ended September 30, 2017 for the change in fair value on revaluation of its warrant liability associated with its warrants issued in conjunction with its stock offering in February 2017. The Company is required to revalue certain of its 2017 warrants at the time of each exercise and at the end of each reporting period and reflect in the statement of operations a gain or loss from the change in fair value of the warrant in the period in which the change occurred. We calculate the fair value of the warrants outstanding using the Black-Scholes and Monte Carlo Simulation models. A gain results principally from a decline in the Company's share price during the period and a loss results principally from an increase in the Company's share price.

**Gain from settlement of liability.** During the period, the Company settled a previously incurred expense utilizing shares of its common stock with an attributed value of \$3 per share. The gain of roughly \$0.2 million reflects the difference in the Company's share price in the open market as of the settlement date and the \$3 per share; which was recorded in the first quarter of 2017.

**Gain from Expiration of Warrants.** The Company recorded a gain during the second quarter of \$1.2 million related to the expiration of warrants issued as part of the February 2017 stock offering.

**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. These convertible promissory notes were all converted into common stock during the second quarter of 2017.

**Net Loss.** The net loss for the nine months ended September 30, 2017 was \$6.6 million which included non-cash expenses of approximately \$3.3 million which included \$2.8 million for change in fair value of warrants liability and \$0.5 million for stock based compensation and depreciation.

## Liquidity and Capital Resources

As of September 30, 2017, we had \$8.7 million in cash and cash equivalents compared to \$5.0 million at December 31, 2016. In February 2017, we completed a public offering of our common stock and warrants, pursuant to which we received approximately \$4.5 million in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. Additionally, through September 30, 2017, \$3.3 million in cash was received from the exercise of warrants issued in our February public offering and \$0.4 million from the sale of common stock in our ATM offering. Cash used in operations was \$4.9 million for the nine months ended September 30, 2017. This increase over prior year of \$2.3 million was mainly due to headcount and general company activity increases, as the Company prepared its IND for Annamycin and readies for the related, upcoming clinical trials during 2017. We believe that our existing cash and cash equivalents as of September 30, 2017 and cash generated already in the fourth quarter will be sufficient to fund our planned operations into the third quarter of 2018. Such plans are subject to change depending on clinical enrollment progress and use of drug product.

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

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

	Nine Months Ended September 30,	
	2017	2016
Net cash used in operating activities	\$ (4,934)	\$ (2,596)
Net cash used in investing activities	(12)	(110)
Net cash provided by financing activities	8,675	8,862
Net increase in cash and cash equivalents	\$ 3,729	\$ 6,156

### *Cash used in operating activities*

Net cash used in operating activities was \$4.9 million for the nine months ended September 30, 2017 compared to \$2.6 million for the same period in 2016. This increase in use of cash for operations is due to our becoming operational post IPO in mid-2016. This mainly included payments made for R&D and 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.

### *Cash used in investing activities*

Net cash used in investing activities was basically nil for the nine months ended September 30, 2017 compared to \$0.1 for the nine months ended September 30, 2016.

### *Cash provided in financing activities*

Net cash provided by financing activities was \$8.7 million for the nine months ended September 30, 2017 compared to \$8.9 million for the nine months ended September 30, 2016. The activity in 2016 is related to our initial public offering stock issuance which raised a net \$8.5 million, issuance of common stock at \$3 per share which raised \$0.7 million, and issuance of convertible notes which raised \$0.2 million. The activity in 2017 is related to the Company's follow-on public offering of common stock and warrants. Of this latter amount, \$3.8 million is related to the exercise of warrants post the follow-on offering.

## **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.

### ***Acquisition***

We acquired Moleculin, LLC on May 2, 2016, and, since such date our financial statements have included the operations of Moleculin, LLC. We account for acquired businesses using the acquisition method of accounting, which requires, among other things, that most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date and that the fair value of acquired in-process research and development (“IPR&D”) be recorded on the balance sheet. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the assigned values of the net assets acquired will be recorded as goodwill. The Company obtained 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.

### ***Research and Development Costs***

We record accrued expenses for estimated costs of our research and development activities conducted by third-party service providers, which include the conducting of pre-clinical studies and the preparation for clinical trials and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and we include these costs in accrued liabilities in the balance sheets and within research and development expense in the 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 may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. To date, there have been no material differences from our accrued expenses to actual expenses.

### ***Impairment of Long-Lived Assets***

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

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS**

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

## **ITEM 4. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures.**

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

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

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

During the last quarter of fiscal 2016, and as our operational activities increased, management determined that it does not have sufficient segregation of duties within its accounting functions, which is a basic internal control. Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals. Management evaluated the impact of our failure to maintain effective segregation of duties on our assessment of our internal control over financial reporting and has concluded that the control deficiency represents a material weakness. Management added a full-time controller during the quarter ended September 30, 2017 and intends to further increase its accounting staff, as soon as economically feasible and sustainable, to remediate this material weakness.

There has been no change in our internal control over financial reporting during our most recent calendar quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II – OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

We are not a party to any pending legal proceedings.

### **ITEM 1A. RISK FACTORS**

For information regarding factors that could affect our results of operations, financial condition and liquidity, refer to the section entitled "Risk Factors" in Part I, Item 1A in our annual report on Form 10-K for the year ended December 31, 2016.

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

On July 29, 2017, we agreed to issue two warrants to purchase 100,000 and 50,000 shares of common stock at exercise prices of \$2.41 and \$3.00 per share, respectively, to a consultant, subject to approval by Nasdaq of a listing of additional shares application, which was received in August 2017. The consultant was an accredited investor.

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.

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 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 in “Item 1. Business” of our Form 10-K for the fiscal year 2016 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 DISCLOSURE**

Not applicable.

**ITEM 5. OTHER INFORMATION.**

None.

## ITEM 6. EXHIBITS

<b>Exhibit Number</b>	<b>Description</b>
10.1	<a href="#"><u>At Market Issuance Sales Agreement, dated September 15, 2017, by and among the Company, Roth Capital Partners, LLC and National Securities Corporation (incorporated by reference to Exhibit 1.1 of the Form 8-K filed September 15, 2017)</u></a>
31.1*	<a href="#"><u>Certification of Principal Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002</u></a>
31.2*	<a href="#"><u>Certification of Principal Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002</u></a>
32.1*	<a href="#"><u>Certification of Principal Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
32.2*	<a href="#"><u>Certification of Principal Officer Financial Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

/\* Filed herewith.

**SIGNATURES**

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

MOLECULIN BIOTECH, INC.

Date: November 13, 2017

By: /s/ Walter V. Klemp

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

Date: November 13, 2017

By: /s/ Jonathan P. Foster

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

**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 13, 2017

By: /s/ Walter Klemp

---

Walter Klemp

Chief Executive Officer

(Principal Executive Officer)

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

I, Jonathan 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 13, 2017

By: /s/ Jonathan P. Foster

---

Jonathan P. Foster  
Executive Vice President and Chief Financial Officer  
(Principal Financial Officer and Principal Accounting  
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 quarter ended September 30, 2017 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Walter Klemp, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 13, 2017

By: /s/ Walter Klemp

\_\_\_\_\_

Walter Klemp

Chief Executive Officer

(Principal Executive Officer)

*A signed original of this written statement required by Section 906 has been provided to Moleculin Biotech, Inc. and will be retained by Moleculin Biotech, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.*

CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-Q for the quarter ended September 30, 2017 of Moleculin Biotech, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonathan Foster, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 13, 2017

By: /s/ Jonathan P. Foster

---

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

*A signed original of this written statement required by Section 906 has been provided to Moleculin Biotech, Inc. and will be retained by Moleculin Biotech, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.*