

**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 **June 30, 2018**

or

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

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

Commission File Number: 001-37758



**MOLECULIN BIOTECH, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**5300 Memorial Drive, Suite 950  
Houston, TX**

(Address of principal executive offices)

**2834**

(Primary Standard Industrial  
Classification Code Number)

**713-300-5160**

(Registrant's telephone number, including area code)

**47-4671997**

(IRS Employer  
Identification Number)

**77007**

(Zip Code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 26,861,497 shares of common stock outstanding at August 1, 2018

**Moleculin Biotech, Inc.**  
**Form 10-Q**  
**For the quarterly period ended June 30, 2018**  
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**PART 1. FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**Moleculin Biotech, Inc.  
Condensed Consolidated Balance Sheets**

(in thousands, except for share and per share data)

	<u>June 30, 2018</u> (Unaudited)	<u>December 31, 2017</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 11,722	\$ 7,714
Prepaid expenses and other	1,170	588
<b>Total current assets</b>	<b>12,892</b>	<b>8,302</b>
Furniture and equipment, net of accumulated depreciation of \$39, and \$21, respectively	26	33
Intangible assets	11,148	11,148
<b>Total assets</b>	<b>\$ 24,066</b>	<b>\$ 19,483</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,676	\$ 810
Accrued expenses and other liabilities	1,839	902
Deferred compensation - related party	150	—
Warrant liability-current	451	503
<b>Total current liabilities</b>	<b>4,116</b>	<b>2,215</b>
Long-term deferred compensation – related party	—	150
Warrant liability - long term	3,202	—
<b>Total liabilities</b>	<b>7,318</b>	<b>2,365</b>
Commitments and contingencies (Note 7)	—	—
<b>Stockholders' equity</b>		
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, 26,861,497 outstanding at June 30, 2018 and 21,469,109 issued and outstanding at December 31, 2017	27	21
Additional paid-in capital	38,247	31,577
Accumulated other comprehensive income	6	—
Accumulated deficit	(21,532)	(14,480)
<b>Total stockholders' equity</b>	<b>16,748</b>	<b>17,118</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 24,066</b>	<b>\$ 19,483</b>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**Moleculin Biotech, Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Income**  
**(Unaudited)**  
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	4,231	515	5,469	1,199
General and administrative	1,220	800	2,611	1,649
Depreciation	7	5	15	8
Total operating expenses	<u>5,458</u>	<u>1,320</u>	<u>8,095</u>	<u>2,856</u>
Loss from operations	<u>(5,458)</u>	<u>(1,320)</u>	<u>(8,095)</u>	<u>(2,856)</u>
Other income (expense):				
Gain (loss) from change in fair value of warrant liability	331	(3,342)	1,040	(2,283)
Gain from settlement of liability	—	—	—	149
Gain from expiration of warrants	—	1,238	—	1,238
Other income (expense)	(1)	—	(1)	(1)
Interest income (expense), net	<u>3</u>	<u>—</u>	<u>4</u>	<u>(1)</u>
Net loss	<u>\$ (5,125)</u>	<u>\$ (3,424)</u>	<u>\$ (7,052)</u>	<u>\$ (3,754)</u>
Net loss per common share – basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.19)</u>	<u>\$ (0.29)</u>	<u>\$ (0.23)</u>
Weighted-average common shares outstanding – basic and diluted	<u>25,888,931</u>	<u>17,863,707</u>	<u>24,617,372</u>	<u>16,137,312</u>
Net Loss	\$ (5,125)	\$ (3,424)	\$ (7,052)	\$ (3,754)
Other comprehensive income (loss):				
Foreign currency translation	6	—	6	—
Comprehensive loss	<u>\$ (5,119)</u>	<u>\$ (3,424)</u>	<u>\$ (7,046)</u>	<u>\$ (3,754)</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	<b>Six Months Ended June 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (7,052)	\$ (3,754)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	15	8
Stock-based compensation	581	219
Deferred compensation - related party	—	63
Change in fair value of warrant liability	(1,040)	2,283
Gain in settlement of liability	—	(149)
Gain from expiration of warrants	—	(1,238)
Loss on foreign currency transactions	1	—
Changes in operating assets and liabilities:		
Prepaid expenses	(582)	(595)
Accounts payable	866	(8)
Accrued expenses and other liabilities	937	(152)
Net Cash Used in Operating Activities	<u>(6,274)</u>	<u>(3,323)</u>
<b>Cash Flows from Investing Activities:</b>		
Purchase of fixed assets	(8)	(4)
Net Cash Used in Investing Activities	<u>(8)</u>	<u>(4)</u>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from exercise of warrants	15	3,132
Proceeds from sale of common stock units, net of cash stock issuance costs	10,269	4,460
Net Cash Provided by Financing Activities	<u>10,284</u>	<u>7,592</u>
Effect of exchange rate changes on cash and cash equivalents	\$ 6	\$ —
Net change in cash and cash equivalents	4,008	4,265
Cash and cash equivalents, at beginning of period	<u>7,714</u>	<u>5,007</u>
Cash and cash equivalents, at end of period	11,722	\$ 9,272
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid for interest	\$ 1	\$ —
Cash paid for taxes	\$ 15	\$ —
Supplemental disclosure of non-cash investing and financing activities:		
Common stock issued for conversion of debt	\$ —	\$ 302
Common stock issued for services provided	\$ —	\$ 89
Warrants exercised – not yet paid	\$ —	\$ 34

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	<u>Common Stock</u>		<u>Additional Paid-In- Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Stockholders' Equity</u>
	<u>Number</u>	<u>Amount</u>				
Balance at December 31, 2017	21,469,109	\$ 21	\$ 31,577	\$ (14,480)	\$ —	\$ 17,118
Warrants exercised	9,752	—	15	—	—	15
Issued for cash - sale of common stock in February 2018, net of issuance costs of \$809	4,290,000	5	5,117	—	—	5,122
Issued for cash - sale of common stock in June 2018, net of issuance costs of \$232	1,092,636	1	957	—	—	958
Stock-based compensation	—	—	581	—	—	581
Net loss	—	—	—	(7,052)	—	(7,052)
Cumulative translation adjustment	—	—	—	—	6	6
Balance at June 30, 2018	<u>26,861,497</u>	<u>\$ 27</u>	<u>\$ 38,247</u>	<u>\$ (21,532)</u>	<u>\$ 6</u>	<u>\$ 16,748</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**Moleculin Biotech, Inc.**  
**Notes to the Consolidated 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, all of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center, which the Company refers to as MD Anderson. MBI has three core drug technologies: a uniquely designed anthracycline (Annamycin), a portfolio of STAT3 inhibitors (WP1066 Portfolio) and a collection of inhibitors of glycolysis (WP1122 Portfolio). The Company's clinical stage drugs are Annamycin, an anthracycline designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML, and WP1066, an immuno-stimulating STAT3 inhibitor targeting primary brain tumors and brain metastases, pancreatic cancer and hematological malignancies. MBI is also engaged in preclinical development of additional drug candidates, including additional STAT3 inhibitors and compounds targeting the metabolism of tumors.

In June 2018, MBI formed Moleculin Australia Pty. Ltd., (MAPL), a wholly-owned subsidiary, to begin preclinical development in Australia for WP1732, an analog of WP1066. This may enable the Company to enjoy the benefits of certain research and development tax credits in Australia.

The Company currently has six drug candidates representing three substantially different approaches to treating cancer. Liposomal Annamycin, which MBI refers to as Annamycin, is a chemotherapy designed to inhibit the replication of DNA of rapidly dividing cells. WP1122 and its analog, WP1234 are inhibitors 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, the Company believes that WP1066, WP1732, and its analog, WP1220, have shown capability, in *in vivo* testing, of altering the cell signaling associated with tumors. The Company has two drugs in three clinical trials.

The Company's most mature drug candidate is Annamycin, an anthracycline being studied for the treatment of relapsed or refractory AML. Annamycin had been in clinical trials pursuant to an investigational new drug application or IND that had been filed with the U.S. Food and Drug Administration, or FDA. Due to a lack of development activity by a prior drug developer, this IND was terminated. To permit the renewed investigation of Annamycin, the Company submitted a new IND for a Phase I/II trial for the treatment of relapsed or refractory AML in August 2017, which the FDA allowed to go into effect in September 2017. The trial in the US is open and is actively recruiting.

The Company has five other drug development projects:

- WP1066 has an approved physician-sponsored clinical trial open for enrollment for the treatment of brain tumors and is also being evaluated for potential treatment of AML and pancreatic cancer,
- WP1220, an analog of WP1066 is being studied for the topical treatment of cutaneous T-cell lymphoma (CTCL) and MBI expects to file a Clinical Trial Application ("CTA") prior to year-end,
- WP1732, another analog of WP1066, that it believes is particularly well suited for intravenous administration, is being evaluated for potential treatment of AML, pancreatic and other cancers, and MBI has begun pre-clinical work which we expect to generate sufficient data for an IND by year-end, and
- WP1122 and WP1234 are being evaluated for their potential to treat brain tumors and pancreatic cancer via their ability to inhibit glycolysis.

The Company has been granted royalty-bearing, worldwide, exclusive licenses for the patent and technology rights related to all of MBI's drug technologies, as these intellectual property rights are owned in part or entirely by MD Anderson. The Annamycin drug substance is no longer covered by any existing patent protection, however, the Company intends to submit patent applications for formulation, synthetic process and reconstitution related to MBI's Annamycin drug product candidate, although there is no assurance that the Company will be successful in obtaining such patent protection. Independently from potential patent protection, MBI has received Orphan Drug designation from the FDA for Annamycin for the treatment of AML, which may provide tax and other benefits during product development and if the product is approved for AML, may lead to a grant of seven-year market exclusivity. Under that exclusivity, which runs from the date of the approval of the New Drug Application (NDA) in the United States, the FDA generally (there are important exceptions) could not approve another Annamycin product for AML. The Company also intends to apply for similar status in the European Union (EU) where market

exclusivity extends to 10 years from the date of Marketing Authorization Application (MAA) approval. Separately, the FDA may also grant market exclusivity of 5 years for newly approved new chemical entities (which the Company believes Annamycin would be one), but there can be no assurance that such exclusivity will be granted.

With regard to additional potential clinical activity, the Company received Polish National Office approval in June 2018 for a Clinical Trial Authorization ("CTA") in Poland, which enables the Company to begin a Phase I/II clinical trial there to study Annamycin for the treatment of relapsed or refractory AML. The Company has one site in Poland open for the trial. This will be in addition to the previously announced allowance of MBI's IND in the United States. The start of clinical trials in Poland is expected to begin in the second half of 2018. In the US, the Company has three sites recruiting patients and ready to provide treatments. Patient treatment began in the US in March of this year. In addition, the Company continues to recruit and contract with clinics both in the United States and Poland. The Company can provide no assurance of additional recruitment or that treatments will occur in the near term and on a timely basis, if at all.

In July 2018, the physician-sponsored WP1066 trial IND for the treatment of glioblastoma opened for recruitment.

On May 1, 2018, the Company engaged another contract research organization ("CRO") to evaluate additional countries for the expansion of our AML clinical trial, specifically Australia and several Western European countries to provide additional clinical sites to improve access for patients to MBI's Phase I/II trial. This evaluation is ongoing.

In September 2017, the Company engaged a CRO to prepare for a proof-of-concept clinical trial in Poland to study its drug candidate WP1220, a part of the WP1066 portfolio, for the treatment of CTCL. The Company filed a CTA in Poland for this use, which if approved, will give the Company its third drug in a clinical trial.

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

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

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

**Basis of Presentation – Unaudited Interim Consolidated Financial Information** - The accompanying unaudited interim consolidated financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for financial information, and in accordance with the rules and regulations of the United States Securities and Exchange Commission (the “SEC”) with respect to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim 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 consolidated financial statements should be read in conjunction with the audited financial statements of the Company as of December 31, 2017 and December 31, 2016 and notes thereto contained in the Form 10-K filed with the SEC on March 28, 2018.

**Principles of consolidation** - The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. As of June 30, 2018, there is only one subsidiary company. All intercompany balances and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to GAAP. The Company views its operations and manages its business in one operating segment. All material long-lived assets of the Company reside in the United States.

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

**Going Concern** - These consolidated financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The continuation of the Company as a going concern is dependent upon the ability of the Company to obtain necessary equity financing to continue operations and the attainment of profitable operations. As of June 30, 2018, the Company has incurred an accumulated deficit of \$21.5 million since inception and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of June 30, 2018 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 consolidated financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements and delay planned cash outlays or a combination thereof. Management cannot be certain that such events or a combination thereof can be achieved.

**Cash and Cash Equivalents** - The Company considers all highly liquid accounts with original maturities of three months or less at the date of acquisition to be cash equivalents. Periodically in the ordinary course of business, the Company may carry cash balances at financial institutions in excess of the insured limits of \$250,000. The amount in excess of the applicable insurance coverage at June 30, 2018 was not material.

**Intangible assets** - Intangible assets with finite lives are amortized using the straight-line method over their estimated period of benefit. If an intangible asset is identified as an in-process research & development (“IPR&D”) asset, then no amortization will occur until the development is complete. If the associated research and development effort is abandoned, the related assets will be written-off and the Company will record a noncash impairment loss on its statements of operations. For those compounds that reach commercialization, if any, the IPR&D assets will be amortized over their estimated useful lives.

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

**Fair Value of Financial Instruments** - The Company's 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.

The Company has categorized its assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy in accordance with 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 its warrant liability discussed in Note 4. In the accompanying consolidated financial statements as of June 30, 2018, the fair value of this warrant liability is included in current liabilities for the 2017 Issuance of Warrants and in long-term liabilities for the February 2018 Issuance of Warrants and the June 2018 Issuance of Warrants. The latter is due to the warrants issued during 2018 having an exercise price substantially higher than the current market value of the Company's stock; therefore, management considers it a long-term liability.

The following table provides the financial assets and liabilities reported at fair value and measured on a recurring basis at December 31, 2017 and June 30, 2018 (in thousands):

Description	Liabilities Measured at Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Fair value of warrant liability as of December 31, 2017:	\$ 503	\$ —	\$ —	\$ 503
Fair value of warrant liability as of June 30, 2018:	\$ 3,653	\$ —	\$ —	\$ 3,653

The table below (in thousands) of Level 3 liabilities begins with the valuation as of the beginning of quarter two and then is adjusted for the issuances and exercises that occurred during the second quarter of 2018 and adjusts for balances for changes in fair value that occurred during the current quarter. The ending balance of the Level 3 financial instrument presented above represents our best estimates and may not be substantiated by comparison to independent markets and, in many cases, could not be realized in immediate settlement of the instruments.

<b>Three months ended June 30, 2018:</b>	<b>Warrant Liability – Current</b>	<b>Warrant Liability – Long-Term</b>	<b>Warrant Liability – Total</b>
Balance, March 31, 2018	\$ 463	\$ 2,410	\$ 2,873
Exercise of warrants	—	—	—
Issuances of warrants	—	1,111	1,111
Change in fair value - net	(12)	(319)	(331)
Balance, June 30, 2018	<u>\$ 451</u>	<u>\$ 3,202</u>	<u>\$ 3,653</u>

The table below (in thousands) of Level 3 liabilities begins with the valuation as of December 31, 2017 and then is adjusted for the issuances, exercises, and the changes in fair value that occurred during the six months ended June 30, 2018. The ending balance of the Level 3 financial instrument presented above represents its 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.

<b>Six months ended June 30, 2018:</b>	<b>Warrant Liability – Current</b>	<b>Warrant Liability – Long-Term</b>	<b>Warrant Liability – Total</b>
Balance, December 31, 2017	\$ 503	\$ —	\$ 503
Exercise of warrants	(13)	—	(13)
Issuances of warrants	—	4,203	4,203
Change in fair value - net	(39)	(1,001)	(1,040)
Balance, June 30, 2018	<u>\$ 451</u>	<u>\$ 3,202</u>	<u>\$ 3,653</u>

**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 months and six months ended June 30, 2018, the Company's potentially dilutive shares, which were not included in the calculation of net loss per share, included options to purchase 2,754,000 common shares and warrants to purchase 3,784,515 common shares as inclusion of these securities would have been anti-dilutive. For the three months and six months ended June 30, 2017, the Company's potentially dilutive shares, which were not included in the calculation of net loss per share, included options to purchase 530,000 common shares and warrants to purchase 948,011 common shares as inclusion of these securities would have been anti-dilutive.

**Reclassifications** – A reclassification was made to the prior period financial statements to conform to the 2018 presentation. Such reclassification did not affect net loss as previously reported. Historically, "accrued expenses and current liabilities" were included in the line item "accounts payable and accrued expenses". Management believes that these costs are best shown as separate line items and, as such, a reclassification was made to the Statement of Cash Flows for the six months ended June 30, 2017 by reducing "Accounts payable" and now creating a new line item "Accrued expenses and other liabilities".

**Subsequent Events** - The Company's management reviewed all material events through the date these consolidated financial statements were issued for subsequent events disclosure consideration and has noted events in notes to the unaudited consolidated financial statements.

#### **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 consolidated 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 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 adoption of this pronouncement did not have a material impact on the Company's consolidated 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 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. The adoption of this pronouncement did not have a material impact on the Company's consolidated 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 adoption of this pronouncement did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718) Improvements to Non-employee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 affects all entities that enter into share-based payment transactions for acquiring goods and services from non-employees. The amendments in this Update expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The

amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption permitted, but no earlier than an entity's adoption date of Topic 606. The Company is currently evaluating the impact that this standard will have on its financial statements.

In July 2018, the FASB issued ASU No. 2018-09, Codification Improvements ("ASU 2018-09"). ASU 2018-09 affects a wide variety of topics in the Codification and applies to all reporting entities within the scope of the affected accounting guidance. The amendments in this Update are effective based on the facts and circumstances of each amendment. Some of the amendments do not require transition guidance and will be effective upon issuance of this Update. However, many of the amendments do have transition guidance with effective dates for annual periods beginning after December 15, 2018, for public business entities. The Company is currently evaluating the impact that this standard will have, if any, on its financial statements.

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

### 3. Accrued Expenses and Other Liabilities

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

	June 30, 2018	December 31, 2017
Accrued license fees and sponsored research agreements	\$ 1,029	\$ 260
Accrued payroll	303	250
Accrued clinical testing	290	320
Accrued legal and professional fees	199	50
Accrued other	18	22
Total accrued expenses and other liabilities	<u>\$ 1,839</u>	<u>\$ 902</u>

### 4. Warrant Liability

The basis of value of the warrant liability is fair value, which is defined pursuant to Accounting Standards Codification ("ASC") 820 to be "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date". The Company used the Black-Scholes option pricing model ("BSM") to determine the fair value of the Series A and Series B Warrants from the February 2017 Issuance, described below, along with the warrants issued in the February 2018 Issuance and June 2018 Issuance. The Company used a Monte Carlo simulation ("MCM") with regard to the Series C Warrants from the February 2017 Issuance because of the path dependent vesting terms of the contract.

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 issuance date.

Estimated volatility is a measure of the amount by which its stock price is expected to fluctuate each year during the expected life of the warrants. Where appropriate, the Company used the historical volatility of peer entities due to the lack of sufficient historical data of its stock price during 2017-2018.

### June 2018 Issuances of Warrants

On June 22, 2018, the Company entered into a definitive agreement with institutional investors for a registered direct offering of securities for the sale of 1,092,636 shares of its common stock, at a purchase price of \$2.105 per share. Concurrently with the sale of the common shares, pursuant to the agreement, the Company also sold warrants to purchase 710,212 shares of common stock. The total number of warrants issued were 742,991, which includes the Roth Warrants below. The Company sold the common shares and warrants for aggregate gross proceeds of approximately \$2.3 million. Subject to certain beneficial ownership limitations, the warrants will be initially exercisable on the six months anniversary of the issuance date at an exercise price equal to \$2.02 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the agreement occurred on June 22, 2018.

The shares of common stock above (but not the warrants or the shares of common stock underlying the warrants) were being offered and sold pursuant to a shelf registration statement (File No. 333-219434) which became effective on August 21, 2017.

The Company also entered into a placement agent agreement (the "Placement Agency Agreement") with Roth Capital Partners, LLC ("Roth"), pursuant to which Roth agreed to serve as exclusive placement agent for the issuance and sale of the common shares and warrants. The Company paid Roth an aggregate fee equal to 6.5% of the gross proceeds received from the sale of the securities in the transactions. Pursuant to the Placement Agency Agreement, it also issued Roth warrants to purchase up to 3% of the aggregate number of shares of common stock sold in the transactions (the "Roth Warrants") or 32,779 shares. The Roth Warrants have substantially the same terms as the investor warrants described above, except that the Roth Warrants will expire on June 21, 2023 and have an exercise price of \$2.3155 per share. The Roth Warrants and the shares issuable upon exercise of the Roth Warrants will be issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and in reliance on similar exemptions under applicable state laws. The Company also reimbursed Roth for its expenses of \$50,000. The Company agreed to give Roth a nine months right of first refusal to act as its lead underwriter or exclusive placement agent for any further capital raising transactions the Company undertakes. With certain exceptions, the Company also granted Roth a six-month tail fee equal to the cash and warrant compensation in the offering, if any investor with which Roth had substantive discussions with respect to the offering, provides MBI with further capital during such six months period following termination of its engagement of Roth.

The assumptions used in the BSM model for the June 2018 warrants are as follows:

	<b>Six Months Ended June 30, 2018</b>	<b>Year Ended December 31, 2017</b>
Risk-free interest rate	2.73%-2.80%	N/A
Volatility	80%	N/A
Expected life (years)	4.97-5.48	N/A
Dividend yield	—%	N/A

A summary of the Company's June 2018 Warrant activity and related information follows:

<b>Description</b>	<b>Number of Shares Under Warrant</b>	<b>Range of Warrant Price per Share</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (Years)</b>
Balance at January 1, 2018	—	—	—	—
Granted	742,991	\$2.02-\$2.32	2.03	5.47
Exercised	—	—	—	—
Expired	—	—	—	—
Balance at June 30, 2018	742,991	\$2.02-\$2.32	2.03	5.47
Vested and Exercisable at June 30, 2018	—	\$2.02-\$2.32	2.03	—

#### **February 2018 Issuance of Warrants**

On February 16, 2018, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors for the sale of 4,290,000 shares of its common stock, at a purchase price of \$2.10 per share. Concurrently with the sale of the common shares, pursuant to the Purchase Agreement, the Company also sold warrants to purchase 2,145,000 shares of common stock. The total number of warrants issued were 2,273,700, which includes the Roth Warrants below. The Company sold the common shares and warrants for aggregate gross proceeds of approximately \$9.0 million. Subject to certain beneficial ownership limitations, the warrants will be initially exercisable on the six-month anniversary of the issuance date at an exercise price equal to \$2.80 per share of common stock, subject to adjustments as

provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the Purchase Agreement occurred on February 21, 2018.

The warrants and the shares issuable upon exercise of the warrants were sold without registration under the Securities Act of 1933 ("Securities Act") in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors, and in reliance on similar exemptions under applicable state laws.

The Company also entered into a placement agent agreement (the "Placement Agency Agreement") with Roth Capital Partners, LLC ("Roth"), pursuant to which Roth agreed to serve as exclusive placement agent for the issuance and sale of the common shares and warrants. The Company paid Roth an aggregate fee equal to 6.5% of the gross proceeds received from the sale of the securities in the transactions. Pursuant to the Placement Agency Agreement, it also issued Roth warrants to purchase up to 3% of the aggregate number of shares of common stock sold in the transactions (the "Roth Warrants") or 128,700 shares. The Roth Warrants have substantially the same terms as the investor warrants described above, except that the Roth Warrants will expire on February 15, 2023. The Roth Warrants and the shares issuable upon exercise of the Roth Warrants will be issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and in reliance on similar exemptions under applicable state laws. The Company also reimbursed Roth for its expenses of \$75,000. The Company agreed to give Roth a nine-month right of first refusal to act as its lead underwriter or exclusive placement agent for any further capital raising transactions it undertakes. With certain exceptions, the Company also granted Roth a six-month tail fee equal to the cash and warrant compensation in the offering, if any investor with which Roth had substantive discussions with respect to the offering, provides MBI with further capital during such six-month period following termination of its engagement of Roth.

The assumptions used in the BSM model for the February 2018 warrants are as follows:

	Six Months Ended June 30, 2018	Year Ended December 31, 2017
Risk-free interest rate	2.71%-2.74%	N/A
Volatility	80%	N/A
Expected life (years)	4.63-5.13	N/A
Dividend yield	—%	N/A

A summary of the Company's February 2018 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, 2018	—	—	—	—
Granted	2,273,700	\$ 2.80	\$ 2.80	5.15
Exercised	—	—	—	—
Expired	—	—	—	—
Balance at June 30, 2018	2,273,700	\$ 2.80	\$ 2.80	5.15
Vested and Exercisable at June 30, 2018	—	\$ 2.80	\$ 2.80	—

#### February 2017 Issuance of Warrants

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 it 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, the Company 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 MBI to cover over-allotments at the public offering price per share of \$1.349 and public offering price per warrant combination of \$0.001, 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. The Company received approximately \$4.5 million in net proceeds from the Offering, after deducting underwriting discounts and commissions and estimated offering expenses.

The assumptions used in the BSM and MCM models for the February 2017 warrants are as follows:

	<b>Six Months Ended June 30, 2018</b>	<b>Year Ended December 31, 2017</b>
Risk-free interest rate	2.66%	1.68%-1.86%
Volatility	80.00%	80.00%-160.11%
Expected life (years)	3.62	0.5-5.0
Dividend yield	—%	—%

A summary of the Company's February 2017 warrant activity and related information follows:

<b>Description</b>	<b>Number of Shares Under Warrant</b>	<b>Range of Warrant Price per Share</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life</b>
Balance at January 1, 2018	419,772	\$1.35-\$1.50	1.46	4.38
Granted	—	— \$	—	—
Exercised	(9,752)	— \$	1.50	—
Expired	—	— \$	—	—
Balance at June 30, 2018	410,020	\$ 1.50	\$ 1.50	3.63
Vested and Exercisable at June 30, 2018	410,020	\$ 1.50	\$ 1.50	3.63

## **Warrant Activity**

The Series B Warrants and the unvested Series C Warrants expired in May 2017. Therefore, the associated warrant liability of \$1.2 million was extinguished on that date and no other Series B Warrants were exercised.

On June 30, 2018, the warrants were revalued with a fair value determination of \$3.7 million which included a fair value adjustment for the three and six months ended of \$0.3 million and \$1.0 million, respectfully, and was included as a gain in "Gain (loss) from change in fair value of warrant liability" in the accompanying financial statements.

## **5. Equity**

The Company is authorized to issue 80,000,000 shares of which 5,000,000 shares of preferred stock are authorized and 75,000,000 shares of common stock are authorized.

### **Preferred Stock**

The Company is authorized to issue up to 5,000,000 shares of preferred stock. Its certificate of incorporation authorizes the board to issue these shares in one or more series, to determine the designations and the powers, preferences and relative, participating, optional or other special rights and the qualifications, limitations and restrictions thereof, including the dividend rights, conversion or exchange rights, voting rights (including the number of votes per share), redemption rights and

terms, liquidation preferences, sinking fund provisions and the number of shares constituting the series. As of June 30, 2018, there was no issued preferred stock.

## Common Stock

### At Market Issuance Sales Agreement (ATM)

On September 15, 2017, the Company entered into an At Market Issuance Sales Agreement (the “ATM Agreement”) with Roth Capital Partners, LLC and National Securities Corporation (collectively, the “Agents”). Pursuant to the terms of the ATM Agreement, it 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.

Any sales of Shares pursuant to the Agreement will be made under its 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 SEC on September 15, 2017. Under the ATM 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 MBI’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 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.

During the six months ended June 30, 2018, the Company did not sell any shares under this Agreement.

### 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 currently 2,500,000 shares. The 2015 Stock Plan was further amended as of April 6, 2018 to increase the number of shares to 4,500,000 shares, and was approved by the Company’s stockholders at the Company’s annual meeting on June 6, 2018. 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 six months ended June 30, 2018:

	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, 2017	1,345,000	\$ 1.93	\$ 3.50	9.07	\$ 83,000
Granted	1,409,000	\$ 1.29	\$ 1.81		
Outstanding, June 30, 2018	2,754,000	\$ 1.80	\$ 2.64	8.77	\$ 91,650
Exercisable, June 30, 2018	200,000	\$ 2.60	\$ 4.81	1.92	\$ 79,500

In January 2018, the Company granted to a new member of its science advisory board options in the aggregate to purchase 10,000 shares of the Company’s common stock with an exercise price of \$1.89 per share, a term of 10 years, and a vesting period of 4 years.

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 \$234,395 for the six months ended June 30, 2018, calculated using the Black-Scholes option-pricing model.

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

	Six Months Ended June 30,	
	2018	2017
Risk-free interest rate	0.95% - 2.24%	1.3% - 2.24%
Volatility	70.18% - 89.11%	70.18% - 89.11%
Expected life (years)	5 to 6.25	6 to 6.25
Expected dividend yield	—	—

Stock-based compensation for the six months ended June 30, 2018 and 2017, are as follows (in thousands):

	3 Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
General and administrative	\$ 293	\$ 108	\$ 502	\$ 216
Research and development	46	2	79	3
<b>Total</b>	<b>\$ 339</b>	<b>\$ 110</b>	<b>\$ 581</b>	<b>\$ 219</b>

Options granted during 2018 have an aggregated fair value of \$1.8 million that was calculated using the Black-Scholes option-pricing model. As of June 30, 2018, total compensation cost not yet recognized was \$3.8 million and the weighted average period over which this amount is expected to be recognized is 3.28 years. No options were exercised in 2018. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the above paragraph and table. The expected term of the options was computed using the "plain vanilla" method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin 107 because the Company does not have sufficient data regarding employee exercise behavior to estimate the expected term. The volatility was determined by referring to the average historical volatility of a peer group of public companies because the Company does 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.

### Consulting Agreement

In 2017, the Company entered into a consulting agreement for its investor relations operations. The consulting agreement initially covered a period of twelve months from the commencement date of July 29, 2017 and was extended in April 2018 until March 31, 2019. Pursuant to the original consulting agreement, in exchange for the consulting services, the Company issued two warrants (collectively, the "Warrants") to purchase 100,000 and 50,000 shares of common stock at exercise prices of \$2.41 and \$3.00 per share.

Each of the Warrants vests over a 12-month period in equal monthly installments starting July 29, 2017, provided that the consultant 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 \$35,278 and \$71,525 for the three and six months ended June 30, 2018 based on the fair value of the warrants vested as of June 30, 2018. In connection with the extension of the consulting agreement, the Company issued the consultant a three-year warrant to purchase 100,000 shares of common stock at an exercise price of \$3.00 per share vesting in four quarterly installments.

### **\$9 million Registered Direct Offering**

On February 16, 2018, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain institutional investors for the sale of 4,290,000 shares of MBI's common stock, at a purchase price of \$2.10 per share. Concurrently with the sale of the common shares, pursuant to the Purchase Agreement, the Company also sold warrants to purchase 2,145,000 shares of common stock. The Company sold the common shares and warrants for aggregate gross proceeds of approximately \$9.0 million. The net proceeds from the transactions was approximately \$8.2 million after deducting certain fees due to the placement agent and transaction expenses. Subject to certain beneficial ownership limitations, the warrants will be initially exercisable on the six-month anniversary of the issuance date at an exercise price equal to \$2.80 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the Purchase Agreement occurred on February 21, 2018.

The Company also entered into a placement agent agreement (the “Placement Agency Agreement”) with Roth Capital Partners, LLC (“Roth”), pursuant to which Roth agreed to serve as exclusive placement agent for the issuance and sale of the common shares and warrants. The Company paid Roth an aggregate fee equal to 6.5% of the gross proceeds received from the sale of the securities in the transactions. Pursuant to the Placement Agency Agreement, it also granted to Roth warrants to purchase up to 3% of the aggregate number of shares of common stock sold in the transactions (the “Roth Warrants”). The Company also reimbursed Roth for its expenses of \$75,000. The Company agreed to give Roth a nine-month right of first refusal to act as its lead underwriter or exclusive placement agent for any further capital raising transactions it undertakes. With certain exceptions, the Company also granted Roth a six-month tail fee equal to the cash and warrant compensation in the offering, if any investor with which Roth had substantive discussions with respect to the offering, provides MBI with further capital during such six-month period following termination of our engagement of Roth.

### **\$2.3 million Registered Direct Offering**

On June 22, 2018, the Company entered into a definitive agreement with institutional investors for a registered direct offering of securities with gross proceeds of approximately \$2.3 million. In connection with the offering, the Company issued 1,092,636 registered shares of common stock at a purchase price of \$2.105 per share. Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from the Company an unregistered warrant to purchase 0.65 of a share of common stock. The warrants have an exercise price of \$2.02 per share, will be exercisable six months from the date of issuance, and will expire five years from the initial exercise date. Roth Capital Partners served as sole placement agent for the offering.

## **6. Income Taxes**

Deferred income tax assets and liabilities are determined based upon differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company does not expect to pay any significant federal, state, or foreign income taxes in 2018 as a result of the losses recorded during the three and six months ended June 30, 2018 and the additional losses expected for the remainder of 2018 and cumulative Net Operating Losses. Accounting standards require the consideration of a valuation allowance for deferred tax assets if it is “more likely than not” that some component or all of the benefits of deferred tax assets will not be realized. As a result, as of June 30, 2018, the Company maintained a full valuation allowance for all deferred tax assets.

The Company recorded no income tax provision for the six months ended June 30, 2018 and 2017. The effective tax rate for the six months ended June 30, 2018 and 2017 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.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the “Tax Act”) was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a federal corporate tax rate decrease from 35% to 21% for tax years beginning after December 31, 2017, the transition of U.S international taxation from a worldwide tax

system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of foreign earnings. As of December 31, 2017, the Company estimated our provision for income taxes in accordance with the Tax Act and guidance available as of the date of the fourth quarter 2017 filing. The amount related to the remeasurement of deferred tax assets and liabilities, based on the rates at which they are expected to reverse in the future, was an expense of \$1.6 million. Since the Company maintains a full valuation allowance against its deferred tax assets, there was no net impact to the Company's earnings on this remeasurement of its gross deferred tax assets. As of the date of the fourth quarter 2017 filing, we asserted that the effects of this remeasurement were a provisional amount in accordance with the guidance of Staff Accounting Bulletin No. 118 ("SAB 118"). As of the June 30, 2018, the Company has determined that no changes are expected to the provisional amount recorded in the fourth quarter of 2017. As such, the Company considers the accounting to be complete as of the first quarter of 2018 for the remeasurement of deferred tax asset and liabilities in accordance with the Tax Act.

## 7. Commitments and Contingencies

In addition to the commitments and contingencies elsewhere in these notes, see below for a discussion of our commitments and contingencies as of June 30, 2018.

### Lease Obligations Payable

On March 22, 2018, the Company entered into a Lease Agreement (the "Lease") with IPX Memorial Drive Investors, LLC (the "Landlord") for the lease of 2,333 rentable square feet "RSF", which it will use for its corporate office space and headquarters. The term of the Lease began in August 2018 for an initial term of 66 months, which may be renewed for an additional 5 years. The Company is required to remit base monthly rent of approximately \$4,300 which will increase at an average approximate rate of 3.00% each year. The Company is also required to pay additional rent in the form of our pro-rata share of certain specified operating expenses of the Landlord. The newly leased space is located in Houston, Texas. The corporate office lease will be classified as an operating lease.

Aggregate annual minimum lease payments under operating leases at June 30, 2018 are as follows (in thousands):

	<b>Year Ended December 31,</b>	
2018	\$	21
2019		52
2020		53
2021		54
2022		55
2023		56
Thereafter		5
Total minimum lease payments	\$	<u>296</u>

### MD Anderson

Under agreements associated with Annamycin, the WP1122 Portfolio, and the WP1066 Portfolio, which includes WP1732, all described below, the Company is responsible for certain license, milestone and royalty payments over the course of the agreements. Annual license fees can cost as high as \$100,000 depending upon the anniversary. Milestone payments for the commencement of phase II and phase III clinical trials can cost as high as \$500,000. Other milestone payments for submission of an NDA to the FDA and receipt of first marketing approval for sale of a license product can be as high as \$600,000. Royalty payments can range in the single digits as a percent of net sales on drug products or flat fees as high as \$600,000, depending upon certain terms and conditions. Not all of these payments are applicable to every drug. Total expenses under these agreements were \$0.1 million and \$0.1 million for the three months ended June 30, 2018 and 2017, respectively, and \$0.2 million and \$0.1 million during the six months ended June 30, 2018 and 2017, respectively.

### Annamycin

In August 2015, the Company 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. On June 29, 2017, the Company entered into an agreement with MD Anderson licensing certain technology related to the method of preparing Liposomal Annamycin.

#### ***WP1122 Portfolio***

The rights and obligations to an April 2012 Patent and Technology License Agreement entered into by and between IntertechBio and MD Anderson (the “IntertechBio Agreement”) have been assigned to MBI. Therefore, MBI has obtained a royalty-bearing, worldwide, exclusive license to intellectual property, including patent rights, related to our WP1122 Portfolio and to our drug product candidate, WP1122.

#### ***WP1066 Portfolio***

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

MBI entered into an out-licensing agreement with Houston Pharmaceuticals, Inc. (“HPI”), pursuant to which 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 MBI must make quarterly sponsored research payments totaling \$0.75 million for the first twelve quarters following the effective date of May 2, 2016, of the HPI Out-Licensing Agreement, or May 2, 2016, in consideration for the right to development data related to the development of licensed products. Notwithstanding 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 (“HPI Repurchase Payment”) MBI 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 sponsored research payments. In the event that MBI does 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 by paying the HPI Repurchase Payment, the license granted to HPI shall convert to an exclusive license upon HPI’s written notice and the Company shall be obligated to transfer all existing data relating to licensed subject matter including any development data and any IND to HPI.

During the quarter ended June 30, 2018, management concluded that it was more likely than not that the Company will pay in the near term the HPI Repurchase Payment. The \$1.0 million accrual for this payment is recorded on the balance sheet as a liability as of June 30, 2018 under “Accrued expenses and other liabilities” and expensed under “Research and development” during the period. Fees related to HPI expensed and the accrual for the HPI Repurchase Payment totaled \$1.1 million and \$0.1 million for the three months ended June 30, 2018 and 2017, respectively, and \$1.2 million and \$0.1 million for the six months ended June 30, 2018, and 2017, respectively.

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

### *Sponsored Research Agreements with MD Anderson*

On January 9, 2017, MBI amended our Sponsored Laboratory Study Agreement with MD Anderson whereby we paid \$0.3 million in 2017, and the agreement was extended to October 31, 2018. On December 4, 2017, MBI extended this Agreement until October 31, 2019 for total payment amount of \$0.35 million spread over that period of time. Of this amount, \$0.24 million was paid in the first quarter of 2018. The final payment of \$0.11 million was paid on August 3, 2018. The expenses recognized under the MD Anderson agreement with regards to the Sponsored Laboratory Study were \$0.09 million and \$0.04 million for the three months ended June 30, 2018 and 2017, respectively, and \$0.18 million and \$0.08 million, for the six months ended June 30, 2018 and 2017, respectively.

### *Employment Agreements*

The Company has agreements with eight employees to provide certain benefits in the event of termination where the base salary and certain other benefits would aggregate approximately \$1.1 million using the rate of compensation in effect at June 30, 2018.

## **8. Subsequent Events**

In addition to the subsequent events discussed elsewhere in these notes, see below for a discussion of our subsequent events occurring after June 30, 2018.

In July 2018, the Company announced it has begun pre-clinical toxicology testing of its WP1732, a fully water-soluble STAT3 inhibitor and a candidate to treat pancreatic cancer, through its new subsidiary in Australia. The Company believes that such work will increase future research and development expenses.

## 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 fund operations and develop our drug candidates;
- The success, including the ability to recruit patients, of our clinical trials through all phases of clinical development;
- The need to obtain regulatory approval of our drug candidates, both in the United States and in Poland;
- Our ability to complete our clinical trials in a timely fashion and within our expected budget;
- Compliance with obligations under intellectual property licenses with third parties;
- Any delays in regulatory review and approval of drug candidates in clinical development;
- Our ability to commercialize our drug candidates;
- Market acceptance of our drug candidates;
- Competition from existing therapies or new therapies that may emerge;
- Potential product liability claims;
- Our dependency on third-party manufacturers to successfully, and timely, supply or manufacture our drug candidates for our preclinical work and our clinical trials;
- Our ability to establish or maintain collaborations, licensing or other arrangements;
- 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 company organized as a Delaware corporation in July 2015 to focus on the development of oncology drug candidates, all of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center, which we refer to as MD Anderson. We have three core drug technologies: a uniquely designed anthracycline (Annamycin), a portfolio of STAT3 inhibitors (WP1066 Portfolio) and a collection of inhibitors of glycolysis (WP1122 Portfolio). Our clinical stage drugs are Annamycin, an anthracycline designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML, and WP1066, an immuno-stimulating STAT3 inhibitor targeting brain tumors, pancreatic cancer and AML. We are also engaged in preclinical development of additional drug candidates, including additional STAT3 inhibitors and compounds targeting the metabolism of tumors.

We currently have six 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 and its analog, WP1234, are inhibitors 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, we believe that WP1066, WP1732, and WP1220 have shown capability, in *in vivo* testing, of altering the cell signaling associated with tumors. We currently have two drugs in three clinical trials.

Our most mature drug candidate is Annamycin, an anthracycline being studied for the treatment of relapsed or refractory AML. Annamycin had been in clinical trials pursuant to an investigational new drug application, or IND, that had been filed with the U.S. Food and Drug Administration, or FDA. Due to a lack of development activity by a prior drug developer, this IND was terminated. To permit the renewed investigation of Annamycin, we submitted a new IND for a Phase I/II trial for the treatment of relapsed or refractory AML in August 2017, which the FDA allowed to go into effect in September 2017. Currently, three sites are open and recruiting patients in this US trial.

We have five other drug development projects:

- WP1066 has an approved physician-sponsored clinical trial open for enrollment for the treatment of brain tumors and is also being evaluated for potential treatment of AML and pancreatic cancer,
- WP1220, an analog of WP1066 is being studied for the topical treatment of cutaneous T-cell lymphoma (CTCL) for which we have filed a CTA in Poland which, if approved, will give us a third drug in clinical trial,
- WP1732, another analog of WP1066 that we believe is particularly well suited for intravenous administration is being evaluated for potential treatment of AML, pancreatic and other cancers, and
- WP1122 and WP1234 are being evaluated for their potential to treat brain tumors and pancreatic cancer via their ability to inhibit glycolysis.

We have been granted royalty-bearing, worldwide, exclusive licenses for the patent and technology rights related to all of our drug technologies, as these intellectual property rights are owned in part or entirely by MD Anderson. The Annamycin drug substance is no longer covered by any existing patent protection, however, we intend to submit patent applications for formulation, synthetic process and reconstitution related to our Annamycin drug product candidate, although there is no assurance that we will be successful in obtaining such patent protection. Independently from potential patent protection, we have received Orphan Drug designation from the FDA for Annamycin for the treatment of AML, which may provide tax and other benefits during product development, and if the product is approved for AML, may lead to a grant of a seven-year market exclusivity. Under that exclusivity, which runs from the date of approval of a New Drug Application (NDA) in the United States, the FDA general (there are important exceptions) could not approve another Annamycin product for AML. We also intend to apply for similar status in the European Union (EU) where market exclusivity extends to 10 years from the date of Marketing Authorization Application (MAA) approval. Separately, the FDA may also grant market exclusivity of 5 years for newly approved new chemical entities (which we believe Annamycin would be), but there can be no assurance that such exclusivity will be granted.

With regard to additional potential clinical activity, we received Polish National Office approval in June 2018 for a CTA in Poland, which enables us to begin a Phase I/II clinical trial there to study with Annamycin for the treatment of relapsed or refractory AML. This will be in addition to the previously announced allowance of our IND in the United States. The start of clinical trials in Poland is expected to begin in the second half of 2018. In the US, we have three sites recruiting patients and ready to provide treatments. Patient treatment began in the US in March 2018. In addition, we continue to recruit and contract with clinics both in the United States and Poland. We can provide no assurance of additional recruitment or that treatments will occur in the near term and on a timely basis, if at all.

We continue to recruit additional clinics into this trial both in the United States and Poland. In the US, we have begun treating patients and have three sites open recruiting and ready to treat patients. We are actively pursuing additional treatment centers, both in the US and in Poland, to increase the access of this trial to potential patients. We can provide no assurance additional sites, recruitment or treatments will occur in the near term and on a timely basis, if at all.

On May 1, 2018, we engaged another CRO to evaluate additional countries for the expansion of our AML clinical trial, specifically Australia and several Western European countries to provide additional clinical sites to improve access for patients to our Phase I/II trial.

In July 2018, the physician-sponsored WP1066 trial IND for the treatment of glioblastoma opened for recruitment in the US.

Furthermore, in September 2017 we engaged a CRO to prepare for a proof-of-concept clinical trial in Poland to study our drug candidate WP1220, a part of the WP1066 portfolio, for the treatment of CTCL. We filed a CTA in Poland for this use which, if approved, will give us a third drug in a clinical trial.

## Corporate Overview

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

Moleculin, LLC was formed in 2006 and was working to develop the WP1066 Portfolio it licensed from MD Anderson. On May 2, 2016, Moleculin, LLC was merged with and into MBI. As a result of the merger, we issued the holders of Moleculin, LLC equity interests and convertible notes 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.

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

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

## Portfolio Status

Below are important developments for each drug/portfolio of MBI.

### *Annamycin*

Our most mature candidate is Annamycin, for which FDA has allowed an IND to go into effect for a Phase I/II trial for the treatment of relapsed or refractory AML and for which the agency has granted Orphan Drug designation for the treatment of AML. We are conducting Phase I/II clinical trials for Annamycin in the US and Poland as a monotherapy for the treatment of relapsed or refractory AML.

### *Clinical Trials for Annamycin*

In October 2016, we adjusted our clinical strategy for Annamycin by adding in a Phase I arm to our trial, which adds expense to our development effort. We believe this change in strategy will add several months to the eventual final approval of the drug, if the drug is approved.

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. We filed our IND application for Annamycin, with the clinical strategy of increasing the maximum tolerable dose mentioned above on February 10, 2017. In subsequent discussions with us, FDA requested certain revisions to the protocol, additional information, and additional data related to Chemistry, Manufacturing and Controls ("CMC"). We made the requested revisions to the protocol and included the CMC data in our re-submission of the IND in August 2017 and the FDA allowed this IND in September 2017.

In August 2017, we met with the European Medicines Agency ("EMA") to discuss a CTA in Europe for the study of Annamycin for the treatment of AML. As a result of that meeting, we decided to proceed with an application in October 2017 for a CTA for Annamycin in Poland. Unlike in the United States, the process for beginning a clinical trial in Poland requires a hospital contract before a request for CTA can be made. We obtained the required hospital contract, which allowed the formal request for Polish approval. In December 2017, the Ethics Committee in Poland approved our Phase I/II trial of Annamycin for the treatment of relapsed or refractory AML. A final approval was required by the Polish National Office which was received in June 2018. The start of clinical trials in Poland is expected to occur in the second half of 2018. We have one site open for clinical trial in Poland. We can provide no assurance that such trial will begin on a timely basis, if at all.

We continue to recruit additional clinics, both in the US and Poland. In the US, we have begun treating patients and have three sites open recruiting and ready to treat patients. We can provide no assurance additional sites, recruitment or treatments will occur in the near term and on a timely basis, if at all.

On May 1, 2018, we engaged another CRO to evaluate additional countries for the expansion of our AML clinical trial, specifically Australia and several Western European countries, to provide additional clinical sites to improve access for patients to our Phase I/II trial. This effort is ongoing.

One of the key dose-limiting toxicities associated with currently available anthracyclines is their propensity to induce life-threatening heart damage. In our current Phase I/II trial for Annamycin, we will collect data to further validate the design intent of Annamycin to have little or no cardiotoxicity.

On March 21, 2017, we received notice that FDA had granted Orphan Drug designation for Annamycin for the treatment of AML, effective March 20, 2017.

### **The WP1066 Portfolio**

We have a license agreement with MD Anderson pursuant to which we have been granted a royalty-bearing, worldwide, exclusive license for the patent and technology rights related to our WP1066 Portfolio and its close analogs, molecules targeting the modulation of key oncogenic transcription factors.

#### *Active and Planned Clinical Testing of WP1066 Portfolio*

In vitro testing has shown a high level of activity for WP1066 against a wide range of solid tumors, and in vivo testing has shown significant activity against head and neck, pancreatic, stomach, and renal cancers, as well as metastatic melanoma and glioblastoma, among others. In vivo testing in mouse tumor models has suggested that WP1066 inhibits tumor growth, blocks angiogenesis (a process that leads to the formation of blood vasculature needed for tumor growth) and increases survival.

With respect to our WP1066 Portfolio, we collaborated with a clinician at MD Anderson who submitted an IND for WP1066 treatment of brain tumors to the FDA. In December 2017, the FDA allowed this application for a Phase I trial of WP1066 in patients with recurrent malignant glioma and brain metastasis from melanoma, to go into effect. This trial opened for recruitment in July 2018.

This Phase I trial with WP1066 drug is mainly funded by \$2 million in private grant funding at MD Anderson which is in addition to two Specialized Programs of Research Excellence (SPOR) peer reviewed grants awarded by the National Cancer Institute. We believe the rigorous peer-review process applied to SPOR grant applications represents an important additional measure of independent assessment and validation of the research connected with our approach to using WP1066 as an inhibitor of STAT3 for the treatment of cancer. The grants described here are not reflected in Moleculin's financial statements, but instead are applied to the cost of pre-clinical and clinical activities at and conducted by MD Anderson.

However, as this is a physician-sponsored clinical trial, we have limited influence on the progression of the trial and, as such, may not be able to prevent disruptions that may delay the treatment of patients with WP1066.

An analog of WP1066, referred to as WP1220, was previously the subject of an IND related to use of the molecule in the topical treatment of psoriasis. Clinical trials were commenced on WP1220 in the US, but were terminated early due to limited efficacy in the topical treatment of psoriatic plaques. Notwithstanding its limitations in treating psoriasis, our pre-clinical research in multiple CTCL cell lines has suggested that WP1220 may be effective in inhibiting CTCL. Based on this data, we are collaborating with a Polish drug development company, Dermin, which has received Polish government grant money to develop WP1220 in Poland for the topical treatment of early stage CTCL patients. CTCL is a potentially deadly form of skin cancer for which there are limited treatment options.

In September 2017, we engaged a CRO to prepare a proof-of-concept clinical trial in Poland to study WP1220 for the topical treatment of CTCL. We filed a CTA in Poland for this use which, if approved, will give us a third drug in a clinical trial.

## The WP1122 Portfolio

We have a license agreement with MD Anderson pursuant to which we have been granted a royalty-bearing, worldwide, exclusive license for the patent and technology rights related to our WP1122 Portfolio and similar molecules targeting the treatment of glioblastoma multiforme ("GBM") and related central nervous system malignancies.

We believe this technology has the potential to target a wide variety of solid tumors, which eventually become resistant to all treatments, and thereby provide a large and important opportunity for novel drugs. Notwithstanding this potential, we are focused on the treatment of central nervous system malignancies and especially GBM. Although less prevalent than some larger categories of solid tumors, cancers of the central nervous system are particularly aggressive and resistant to treatment. The prognosis for such patients can be particularly grim and the treatment options available to their physicians are among the most limited of any cancer.

We have preliminary preclinical data for WP1122, including in vitro activity against cancer cell lines, as well as data on survival of animals subjected to xenografts of human brain tumors, including data regarding biodistribution and pharmacokinetics. In non-optimal doses and treatment regimes, WP1122 performed equal to or better than the current market leader, temozolomide and provided for superior survival of animals treated in combination with temozolomide. Notwithstanding these early results, we recognize that substantial additional preclinical and clinical research remains to be done and may not support these initial findings or their translation into activity in humans. We have begun planning the necessary pre-clinical work for WP1122.

Our current sponsored research agreement with MD Anderson is funding further research on WP1234, which is being evaluated for its potential to treat brain tumors and pancreatic cancer via its ability to inhibit glycolysis.

## Recent Business Developments

Below are recent business developments.

### *Moleculin Seeks Approval from Polish Regulatory Agency for Skin Cancer Clinical Trial*

On August 9, 2018, we announced that we had submitted a request to Polish authorities for clinical trial authorization for our STAT3 inhibitor, WP1220, for the treatment of Cutaneous T-Cell Lymphoma. This request for CTA, if approved, will give us a third drug in clinic. Published research supports the belief that Cutaneous T-Cell Lymphoma, a deadly form of skin cancer, may be highly dependent on the upregulation of the activated form of STAT3. We believe WP1220 may be ideally suited as a topical agent to inhibit STAT3 and therefore could potentially become a valuable new drug for the treatment of CTCL. A request for CTA in Poland is the equivalent of a request for Investigational New Drug status in the U.S. This follows our announcement in June 2018 of the approval of a CTA in Poland for our drug Annamycin for the treatment of AML.

### *Moleculin Announces Enrollment Opens for Brain Tumor Trial of WP1066*

On July 31, 2018, we announced enrollment opened for a physician-sponsored clinical trial of WP1066 for the treatment of glioblastoma and brain metastases in adults. This is the first investigator-initiated trial of WP1066, an important milestone. The goal of this clinical research study is to find the highest tolerable dose of WP1066 that can be given to patients with recurrent (has returned after treatment) cancerous brain tumors or melanoma that has spread to the brain. The safety of this drug will also be studied. WP1066 is designed to target the STAT3 pathway in cancer cells, which independent research has shown allows these cells to survive and proliferate, increases new blood vessels to the tumor, causes the cancer cells to move throughout the body and brain, and reduces the ability of the immune system to effectively combat tumor development. In addition, we believe that WP1066 may also have the potential to stimulate a natural anti-tumor immune response.

### *Announcements Involving our STAT3 Inhibitor WP1066 Portfolio which includes WP1732*

In February 2018, we announced that, pursuant to our continued collaboration with MD Anderson we had developed and licensed what we believe, based on pre-clinical testing, may be a potential breakthrough - WP1732, a new molecule in the WP1066 portfolio - in our effort to develop a new cancer treatment that selectively kills highly resistant tumors. We believe this new discovery could improve our ability to treat a broader range of the most difficult cancers, and especially pancreatic cancer. Specifically, we have preclinical evidence to suggest this new molecule is capable of controlling a process known as 'ubiquitination' to block the activated form of STAT3, an important oncogenic transcription factor.

In July 2018, we announced we had begun pre-clinical toxicology testing of WP1732, a fully water-soluble STAT3 inhibitor and a candidate to treat pancreatic cancer, through our new subsidiary in Australia. By utilizing our subsidiary in Australia and the attractive R&D tax credits it offers, we believe we can accelerate the pre-clinical work of WP1732. We anticipate completing the filing and approval of this IND in 2019. We can provide no assurance that such filing and, ultimately, approval of this IND will occur on a timely basis or if at all.

In June 2018, we announced that we had entered into an agreement with the Jagiellonian University in Krakow, Poland, for the development of our STAT3 inhibitor, WP1732, for the treatment of ocular tumors. We believe that there are very limited options for the treatment of ocular tumors. We believe that the water soluble nature of WP1732 could make it an ideal candidate for targeting these unique and highly metastatic tumors.

Also in June 2018, we announced that we entered into an agreement with The University of Iowa Pharmaceuticals for the development of a formulation for WP1732. WP1732, which we believe, based on pre-clinical testing, may be a breakthrough discovery, is now advancing to the stage of formulation development. We believe that this agreement marks the beginning of our creating a pre-clinical package to submit to the FDA in order to request Investigational New Drug status.

#### *\$2.3 million Registered Direct Offering*

On June 22, 2018, we entered into an agreement with institutional investors for a registered direct offering of securities with gross proceeds of approximately \$2.3 million. Concurrently, with the sale of common shares, pursuant to the agreement, we also sold warrants to purchase 710,212 shares of common stock. Subject to certain beneficial ownership limitations, the warrants will be initially exercisable on the six-month anniversary of the issuance date at an exercise price equal to \$2.02 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the agreement closed on June 22, 2018.

#### *\$9 million Registered Direct Offering*

On February 16, 2018, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors for the sale by us of 4,290,000 shares of our common stock, at a purchase price of \$2.10 per share. Concurrently with the sale of the common shares, pursuant to the Purchase Agreement, we also sold warrants to purchase 2,145,000 shares of common stock. We sold the common shares and warrants for aggregate gross proceeds of approximately \$9.0 million with net proceed approximating \$8.2 million. Subject to certain beneficial ownership limitations, the warrants will be initially exercisable on the six-month anniversary of the issuance date at an exercise price equal to \$2.80 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the Purchase Agreement closed on February 21, 2018.

#### *Lease Agreement*

On March 22, 2018, we entered into a Lease Agreement (the "Lease") with IPX Memorial Drive Investors, LLC (the "Landlord") for the lease of 2,333 rentable square feet "RSF", which we are using for corporate office space and headquarters. The term of the Lease began in August 2018 and will continue for an initial term of 66 months, which may be renewed for an additional 5 years. We are required to remit base monthly rent of approximately \$4,300 which will increase at an average approximate rate of 3% each year. We are also required to pay additional rent in the form of our pro-rata share of certain specified operating expenses of the Landlord. The newly leased space is located in Houston, Texas.

## Results of Operations

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues	\$ —	\$ —	\$ —	\$ —
Operating Expenses:				
Research and development	4,231	515	5,469	1,199
General and administrative	1,220	800	2,611	1,649
Depreciation	7	5	15	8
Total operating expenses	5,458	1,320	8,095	2,856
Loss from operations	(5,458)	(1,320)	(8,095)	(2,856)
Other income (expense):				
Gain (loss) from change in fair value of warrant liability	331	(3,342)	1,040	(2,283)
Gain from settlement of liability	—	—	—	149
Gain from expiration of warrants	—	1,238	—	1,238
Other expense	(1)	—	(1)	(1)
Interest income (expense), net	3	—	4	(1)
Net loss	\$ (5,125)	\$ (3,424)	\$ (7,052)	\$ (3,754)

### *Three Months Ended June 30, 2018 compared to three months ended June, 2017*

**Research and Development Expense.** Research and development (R&D) expense was \$4.2 million and \$0.5 million for the three months ended June 30, 2018 and 2017, respectively. The increase of approximately \$3.7 million mainly represents an increase of approximately: \$2.3 million associated with the one-time costs of producing additional drug product for our Annamycin clinical trials, including product for the expansion beyond the currently planned Phase I/II clinical trial, and with pre-clinical work on WP1732 in anticipation of filing an IND in 2019, \$1.0 million accrued expense related to the HPI Option Repurchase Payment, \$0.2 million related to an increase in R&D associated headcount costs and \$0.2 million related to various other expenses. We believe that the R&D expenditures associated with WP1732 in Australia will generate Australian income tax credits next calendar year for which cash should be received by our Australian subsidiary in 2019.

**General and Administrative Expense.** General and administrative expense was \$1.2 million and \$0.8 million for the three months ended June 30, 2018 and 2017, respectively. The increase of approximately \$0.4 million was mainly attributable to the increase in headcount and associated payroll costs of \$0.3 million, and \$0.1 million of stock-based compensation. Such increases are due to the increased corporate activity as we enter clinical trials and increase our pre-clinical work on WP1732.

**Gain from Change in Fair Value of Warrant Liability.** We recorded a net gain of \$0.3 million in the second quarter of 2018 as compared to a loss of approximately \$3.3 million in 2017, for the change in fair value on revaluation of our warrant liability associated with our warrants issued in conjunction with our stock offerings in June 2018, February 2018, and February 2017. We are required to revalue certain of the warrants at the time of each warrant exercise and at the end of each reporting period and reflect in the statement of operations a gain or loss from the change in fair value of the warrant in the period in which the change occurred. We 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 our share price during the period and a loss results principally from an increase in our share price.

**Net Loss.** The net loss for the three months ended June 30, 2018 was \$5.1 million, which included non-cash income of \$0.3 million on the gain in fair value of our warrant liability, which was offset by noncash charges for \$0.3 million related to stock-based compensation and other stock-based expenses.

*Six Months Ended June 30, 2018 compared to six months ended June, 2017*

**Research and Development Expense.** R&D expense was \$5.5 million and \$1.2 million for the six months ended June 30, 2018 and 2017, respectively. The increase of approximately \$4.3 million mainly represents an increase of approximately: \$2.6 million associated with one-time costs of producing additional drug product for our Annamycin clinical trials, including product for the expansion beyond the currently planned Phase I/II clinical trial, and with pre-clinical work on WP1732 in anticipation of filing an IND in 2019, \$1.0 million related to the HPI Option Repurchase Payment, \$0.4 million related to an increase in R&D associated headcount costs, \$0.1 million related to increased travel associated with the increased corporate activity, and \$0.2 million related to various other expenses. We believe that the R&D expenditures associated with WP1732 in Australia will generate Australian income tax credits next calendar year for which cash should be received by our Australian subsidiary in 2019.

**General and Administrative Expense.** General and administrative expense was \$2.6 million and \$1.6 million for the six months ended June 30, 2018 and 2017, respectively. The increase of approximately \$1.0 million was mainly attributable to the increase in headcount and associated payroll costs of \$0.4 million; \$0.3 million of stock-based compensation; increased consulting fees of \$0.2 million; and, approximately \$0.1 million in other expenses. Such increases are due to the increased corporate activity as we enter clinical trials and increase our pre-clinical work on WP1732.

**Gain from Change in Fair Value of Warrant Liability.** We recorded a net gain of \$1.0 million in the first six months of 2018 as compared to a net loss of approximately \$2.3 million in 2017, for the change in fair value on revaluation of our warrant liability associated with our warrants issued in conjunction with our stock offerings in June 2018, February 2018, and February 2017. We are required to revalue certain of the warrants at the time of each warrant exercise and at the end of each reporting period and reflect in the statement of operations a gain or loss from the change in fair value of the warrant in the period in which the change occurred. We 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 our share price during the period and a loss results principally from an increase in our share price.

**Net Loss.** The net loss for the six months ended June 30, 2018 was \$7.1 million, which included non-cash income of \$1.0 million on the gain in fair value of our warrant liability, which was offset by noncash charges for \$0.6 million related to stock-based compensation and other stock-based expenses.

## Liquidity and Capital Resources

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

	Six Months Ended June 30,	
	2018	2017
Net cash used in operating activities	\$ (6,274)	\$ (3,323)
Net cash used in investing activities	(8)	(4)
Net cash provided by financing activities	10,284	7,592
Effect of exchange rate changes on cash and cash equivalents	6	\$ —
Net increase in cash and cash equivalents	\$ 4,008	\$ 4,265

### *Cash used in operating activities*

Cash used in operations was \$6.3 million for the six months ended June 30, 2018. This increase over the prior year of \$3.0 million was mainly due to an increase in headcount and general company activity as we began our U.S. clinical trial for Annamycin, began working on expanding the trial outside of the US, and began pre-clinical work on WP1732.

### *Cash used in investing activities*

Net cash used in investing activities was basically nil for the six months ended June 30, 2018 compared to \$0.004 million for the six months ended June 30, 2017.

### *Cash provided in financing activities*

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

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

In February 2017, we completed a public offering of our common stock and warrants, pursuant to which we received approximately \$5.2 million in net proceeds after exercise of a portion of the warrants and deducting underwriting discounts and commissions and estimated offering expenses. Additionally, in the six months ended June 30, 2018, \$15,000 in cash was received from the exercise of warrants issued in our February 2017 public offering.

We believe that our existing cash and cash equivalents as of June 30, 2018 will be sufficient to fund our planned operations into the second quarter of 2019. 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.

## **Critical Accounting Policies and Significant Judgments and Estimates**

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

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

### ***Acquisition***

We acquired Moleculin, LLC on May 2, 2016, and, since such date our consolidated financial statements have included the operations of Moleculin, LLC. In June 2018, MBI formed Moleculin Australia Pty. Ltd., (MAPL), a wholly-owned subsidiary, to begin preclinical development in Australia for WP1732. This may enable us to enjoy the benefits of certain research and development tax credits in Australia. We account for acquired businesses using the acquisition method of accounting, which requires, among other things, that most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date and that the fair value of acquired in-process research and development (“IPR&D”) be recorded on the balance sheet. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the assigned values of the net assets acquired will be recorded as goodwill. We obtained input from third-parties regarding our tangible and intangible assets and other information necessary to measure the fair value of the assets acquired and liabilities assumed in connection with the acquisition of Moleculin, LLC.

### ***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 consolidated financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, we believe that the consolidated financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

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

During the last quarter of fiscal 2016, and as our operational activities increased, management determined that it does not have sufficient segregation of duties within its accounting functions, which is a basic internal control. Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals. Management evaluated the impact of our failure to maintain effective segregation of duties on our assessment of our internal control over financial reporting and has concluded that the control deficiency represents a material weakness. Management added a full-time controller in September 2017 and a Senior Accountant in February 2018. Furthermore, in June 2018, the Company began the process of replacing its accounting system with a more robust accounting system that should assist in mitigating this material weakness. Management intends to further increase its accounting staff and complete the implementation of the new accounting system, 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

None.

### ITEM 1A. RISK FACTORS

For information regarding factors that could affect our results of operations, financial condition and liquidity, refer to the section entitled "Risk Factors" in Part I, Item 1A in our annual report on Form 10-K for the year ended December 31, 2017. Except as updated below, there have been no material changes from the risk factors previously disclosed in our annual report on Form 10-K for the year ended December 31, 2017 as filed with the SEC.

**We conduct significant operations through our Australia wholly-owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations will suffer.**

In June 2018, we formed a wholly-owned Australian subsidiary, Moleculin Australia Pty Ltd, or (MAPL), to begin preclinical development in Australia for WP1732, an analog of WP1066. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop and commercialize our drug products in Australia, including conducting preclinical studies and

clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our drug candidates in Australia will be accepted by the FDA or foreign regulatory authorities for development and commercialization approvals.

In addition, current Australian tax regulations provide for a refundable research and development tax credit equal to 43.5% of qualified expenditures. If we are ineligible or unable to receive the research and development tax credit, or if we lose our ability to operate MAPL in Australia, or the Australian government significantly reduces or eliminates the tax credit, our business and results of operations would be adversely affected.

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

On May 9, 2018, we agreed to issue a warrant to purchase 100,000 shares of common stock at an exercise price of \$3.00 per share to a consultant. The consultant is an accredited investor. We believe that the issuance was 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 June 20, 2018, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors for the sale of 1,092,636 shares of our common stock, at a purchase price of \$2.105 per share. Concurrently with the sale of the common shares, pursuant to the Purchase Agreement, we also sold to the investors warrants to purchase 710,212 shares of common stock. We sold the common shares and warrants for aggregate gross proceeds of approximately \$2.3 million. Subject to certain beneficial ownership limitations, the warrants will be initially exercisable on the six-month anniversary of the issuance date at an exercise price equal to \$2.02 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the Purchase Agreement closed on June 22, 2018.

The net proceeds from the transactions was approximately \$2.1 million after deduction certain fees due to the placement agent and transactions expenses. The net proceeds will be used for planned clinical trials, preclinical programs, for other research and development activities and for general corporate purposes.

The common shares were offered and sold by us pursuant to an effective shelf registration statement on Form S-3, which was filed with the SEC on July 24, 2017 and subsequently declared effective on August 21, 2017 (File No. 333-219434), and the base prospectus contained therein. We filed a prospectus supplement with the SEC on June 21, 2018, in connection with the sale of the common shares.

The warrants and the shares issuable upon exercise of the warrants were sold without registration under the Securities Act in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering to accredited investors, and in reliance on similar exemptions under applicable state laws.

We also entered into a placement agent agreement (the "Placement Agency Agreement") with Roth Capital Partners, LLC ("Roth"), pursuant to which Roth agreed to serve as exclusive placement agent for the issuance and sale of the common shares and warrants. We paid Roth an aggregate fee equal to 6.5% of the gross proceeds received by us from the sale of the securities in the transactions. Pursuant to the Placement Agency Agreement, we also agreed to grant to Roth or its designees warrants to purchase up to 3% of the aggregate number of shares of common stock sold in the transactions (the "Roth Warrants"). The Roth Warrants have substantially the same terms as the warrants, except that the Roth Warrants have an exercise price of \$2.3155 and will expire on June 20, 2023. The Roth Warrants and the shares issuable upon exercise of the Roth Warrants will be issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and in reliance on similar exemptions under applicable state laws.

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

## **ITEM 4. MINE SAFETY DISCLOSURE**

Not applicable.

**ITEM 5. OTHER INFORMATION.**

On August 9, 2018, we announced that we had submitted a request to Polish authorities for clinical trial authorization ("CTA") for our STAT3 inhibitor, WP1220, for the treatment of Cutaneous T-Cell Lymphoma ("CTCL"). This request for CTA, if approved, will give us the third drug in clinic. Published research supports the belief that Cutaneous T-Cell Lymphoma, a deadly form of skin cancer, may be highly dependent on the upregulation of the activated form of STAT3. We believe WP1220 may be ideally suited as a topical agent to inhibit STAT3 and therefore could potentially become a valuable new drug for the treatment of CTCL. A request for CTA in Poland is the equivalent of a request for Investigational New Drug (IND) status in the U.S. This follows our announcement in June of this year of the approval of a CTA in Poland for its drug Annamycin for the treatment of acute myeloid Leukemia ("AML").

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
4.1	<a href="#"><u>Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Form 8-K filed June 21, 2018)</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 Accounting and Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</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: August 10, 2018

By: /s/ Walter V. Klemm

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

Date: August 10, 2018

By: /s/ Jonathan P. Foster

Jonathan P. Foster,  
Executive Vice President & 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.

August 10, 2018

By: /s/ Walter V. 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.

August 10, 2018

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 June 30, 2018 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: August 10, 2018

By: /s/ Walter V. 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 June 30, 2018 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: August 10, 2018

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.*