
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

DATE OF REPORT (DATE OF EARLIEST EVENT REPORTED): AUGUST 14, 2017

MOLECULIN BIOTECH, INC.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE
(State or Other Jurisdiction of
Incorporation or Organization)

001-37758
(Commission File No.)

47-4671997
(I.R.S. Employer Identification No.)

2575 WEST BELLFORT, SUITE 333, HOUSTON TX 77054
(Address of principal executive offices and zip code)

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

(Former name or former address, if changed from last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02. Results of Operations and Financial Condition.

On August 14, 2017, Moleculin Biotech, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2017 and recent operational highlights. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be “filed” for purpose of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
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99.1	Moleculin Biotech, Inc. press release dated August 14, 2017
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SIGNATURE

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MOLECULIN BIOTECH, INC.

Date: August 14, 2017

By: /s/ Jonathan Foster
Jonathan Foster
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Moleculin Biotech, Inc. press release dated August 14, 2017



Moleculin Biotech, Inc. Reports Financial Results for the Second Quarter Ended June 30, 2017

HOUSTON – August 14, 2017 – Moleculin Biotech, Inc., (NASDAQ: MBRX) ("Moleculin" or the "Company"), a preclinical pharmaceutical company focused on the development of anti-cancer drug candidates, some of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center ("MD Anderson"), today announced its financial and operating results for the second quarter ended June 30, 2017 and other recent developments.

Walter Klemp, Chairman and CEO of Moleculin stated: *"We are pleased with the results of this past quarter, especially in our recent achievements with the Mayo Clinic to supply WP1066 for a potential grant funded study, a discovery of a Metabolic Inhibitor with the potential to treat pancreatic cancer and signing a new technology license agreement with MD Anderson. We are also excited to have begun clinical testing site development efforts in Poland with our appointment of Bioscience SA as our Polish CRO. We look forward to submitting our IND for Annamycin for the treatment of relapsed or refractory AML and moving forward with the FDA to allow for clinical trials to begin."*

Mr. Klemp continued: *"The recent approvals of three new drugs (Rydapt, Vyxeos and Idhifa) for the treatment of AML are exciting, since they provide additional options for treatments in defined subpopulations, and because they help underscore the magnitude of the potential opportunity for Annamycin, which we will be studying for relapsed or refractory AML. With regard to AML, Rydapt is approved only for patients with a specific gene mutation, and for use in combination with the standard of care chemotherapy. Vyxeos is approved as an option to the standard of care, but only for specific AML patients, namely those with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC). Jazz Pharmaceuticals purchased this drug in their \$1.5 billion acquisition of Celator Pharmaceuticals.*

"Although FDA approval of both of those drugs was based on overall survival comparisons with a standard of care, Idhifa was approved based on an accelerated clinical trial design that showed a 19% response rate in patients with relapsed or refractory AML and IDH2 mutation. What's interesting is that Idhifa was approved with a single Phase 1/2 clinical trial based on response rate, not overall survival, and a relatively low response rate at that. Also, the patient population for which it is approved represents only 13% of all AML patients. We look forward to working with FDA on a similar approach for Annamycin – reliance on response rate in an accelerated path – but for a larger population of AML patients."

"While these new drugs make valuable incremental improvements in AML therapy," concluded Mr. Klemp, "most AML patients will still fail to respond to (or relapse from) initial therapy; therefore, our initial clinical development plan will attempt to address the significant unmet need of patients who relapse from, or are refractory to, initial therapy. We also believe that, if Annamycin can demonstrate superior efficacy and safety to the current standard of care, the drug may be able to fill major areas for first-line AML treatment. In the meantime, these transactions serve to remind us of the opportunity for our company if Annamycin shows significant activity in our planned clinical trials."

Jonathan P. Foster, EVP and CFO of Moleculin stated: “We are extremely pleased with the ongoing support of our shareholder base. Late in the quarter and up to the first week in August we saw exercise activity of over 2 million warrants which will generate over \$3 million in cash for the Company. The overhang of over 8 million warrants generated from our February offering is now below 500,000. As such, we are pleased to report that we believe we now have sufficient funds to pursue our planned operations into the second quarter of 2018.”

Second Quarter & Recent Highlights

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

Announced the Discovery of a Metabolic Inhibitor with the Potential to Treat Pancreatic Cancer – The Company announced on June 21, 2017, that it has received attention from the scientific community for its glucose decoy technology as a potential means to starve tumors to death by exploiting their hyper-dependence on glycolysis for energy production. The Company has identified possible new properties of its compound WP1234, a modification to WP1122. In pre-clinical testing, WP1234 has shown improved drug characteristics when compared with WP1122 and a 20 to 50-fold greater ability to kill pancreatic cancer cell lines when compared with traditional inhibitors of glycolysis. The Company believes this discovery now makes WP1234 a promising drug candidate to be studied for the treatment of pancreatic cancer.

Closing of a Follow-On Public Offering – In February 2017, we completed a public offering of our common stock and warrants, pursuant to which we received \$4.5 million in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. On March 24, 2017, warrants associated with this offering were exercised generating an additional \$0.80 million in net proceeds. During the second quarter of 2017, warrants associated with this offering were exercised generating an additional \$2.4 million bringing the total net proceeds from this offering to above \$7.6 million.

Regained Nasdaq Compliance - On July 6, 2017, the Company received a letter from NASDAQ notifying us that we had regained compliance with NASDAQ Listing Rule 5550(a)(2) as a result of the closing bid price for the Company’s common stock being at \$1.00 or more for a minimum of 10 consecutive business days. On May 18, 2017, the Company received a prior deficiency letter from NASDAQ notifying us that for the last 30 consecutive business days, the bid price for the Company’s common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on the Nasdaq Capital Market.

Signed a new technology license agreement with MDA Cancer Center - On July 18, 2017, the Company announced a new technology license agreement with MDA Cancer Center based on new patent applications the Company intends to file relating to its drug Annamycin for the treatment of relapsed or refractory AML.

John M. Climaco Added to the Board of Directors – The Company announced the appointment of John M. Climaco as an independent member of the Company's Board of Directors, effective July 24, 2017 to fill a board vacancy. John M. Climaco, JD, 48, was most recently the Executive Vice President of Perma-Fix Medical S.A, a Polish subsidiary of the Perma-Fix Environmental Services, Inc. (NASDAQ: PESI) where he has served as a director since 2013. From 2003 to 2012, Mr. Climaco served as President and Chief Executive Officer, as well as a member of the Board of Directors of Axial Biotech, Inc., a venture-backed molecular diagnostics company specializing in spine disorders, which he cofounded in 2003. Since 2012, Mr. Climaco has served as a member of the Board of Directors for Digirad Corporation (NASDAQ: DRAD). Mr. Climaco has previously served as a board member for PDI, Inc. (NASDAQ: PDII and as a board member for InfuSystem Holdings, Inc. (NASDAQ: INFU). From 2001 to 2007, he practiced law for the firm of Fabian and Clendenin, specializing in corporate and tax legal strategies for diverse clients across the U.S. and Europe, as well as joint venture, corporate and securities transactions. Mr. Climaco earned his B.A. in Philosophy from Middlebury College, Cum Laude, and holds a J.D. from the University of California Hasting College of the Law.

Moleculin Begins Clinical Testing Site Development Efforts in Poland - On August 3, 2017, the Company announced it had appointed Bioscience SA (“Bioscience”), a Polish contract research organization (“CRO”) to begin identifying and preparing clinical testing sites in Poland for its drug Annamycin for the treatment of relapsed or refractory AML.

Planned Activities and Upcoming Potential Milestones

Anticipated Milestone	Potential Timeframe
Announcement that our IND for Annamycin has become effective and that we may begin clinical trials	September 2017
Initial IRB (Institutional Review Board) approvals and site initiations of various clinical sites participating in our Phase I/II clinical trial of Annamycin	Second Half of 2017
Establishment of a new MTD for Annamycin	First Half of 2018
A clinician sponsored IND for WP1066 for treatment of adult brain tumors moving forward	Second Half of 2017
Announcement of Phase II data for Annamycin	2018
Announcement of further benefits of our sponsored research agreement with MD Anderson	2018

Unaudited Financial Results for the Quarter Ended June 30, 2017

Research and Development Expense. Research and development (R&D) expense was \$0.5 million and \$0.1 million for the three months ended June 30, 2017 and 2016, respectively. The increase of approximately \$0.4 million mainly represents an increase of approximately: \$0.1 million related to an increase in R&D headcount and associated headcount costs; \$0.1 million for sponsored research and related expenses; and, approximately \$0.2 million associated with developing and testing drug product as we prepare our IND for Annamycin and for the related clinical trials.

General and Administrative Expense. General and administrative expense was \$0.8 million and \$0.6 million for the three months ended June 30, 2017 and 2016, respectively. The expense increase of approximately \$0.2 million was mainly attributable to the increase in headcount and associated payroll costs of \$0.2 million, including roughly \$0.1 million of stock based compensation; and, approximately \$0.1 million in legal, accounting, consulting, and other professional expenses. This was offset by a reduction in public listing expense of \$0.3 million as we completed our IPO in Q2 2016.

Loss from Change in Fair Value of Warrant Liability. The Company recorded a net loss of \$3.3 million in the second quarter of 2017 for the change in fair value on revaluation of its warrant liability associated with the warrants issued in conjunction with its stock offering in February 2017. The Company is required to revalue certain of its 2017 warrants at the end of each reporting period and reflect in the statement of operations a gain or loss from the change in fair value of the warrant in the period in which the change occurred. We calculate the fair value of the warrants outstanding using the Black-Scholes and Monte Carlo Simulation models. A gain results principally from a decline in the Company's share price during the period and a loss results principally from an increase in the Company's share price.

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

Interest expense. Interest expense included expense accrued on our convertible promissory notes issued in 2015 and 2016 bearing interest at the rate of 8% per annum. These convertible promissory notes were all converted into common stock during the second quarter of 2017.

Net Loss. The net loss for the three months ended June 30, 2017 was \$2.3 million, which included non-cash income of \$1.2 million related to a gain recognized on the expiration of warrants, which was offset by a non-cash expense of approximately \$3.3 million on the change in fair value of the Company's warrant liability. The net loss also included additional noncash charges for \$0.1 million for stock based compensation and other stock based expenses.

Six Months Ended June 30, 2017 compared to six months ended June 30, 2016

Research and Development Expense. R&D expense was \$1.2 million and \$0.1 million for the six months ended June 30, 2017 and 2016, respectively. The increase of approximately \$1.1 million mainly represents an increase of approximately: \$0.2 million related to an increase in R&D headcount and associated payroll costs; \$0.2 million for sponsored research and related expenses; approximately \$0.2 million associated with developing and testing drug product as we prepare for clinical trials; and, \$0.5 million related to travel, legal, consultants, and other research costs associated in preparing our IND and Orphan Drug applications with the FDA.

General and Administrative Expense. General and administrative expense was \$1.7 million and \$0.9 million for the six months ended June 30, 2017 and 2016, respectively. The expense increase of approximately \$0.7 million was mainly attributable to the increase in headcount and associated payroll costs of \$0.5 million including roughly \$0.2 million of stock based compensation; approximately \$0.3 million in legal, accounting, consulting, and other professional expenses; approximately \$0.1 million in insurance expense; and roughly \$0.1 million in travel expenses. These costs were offset by a reduction in public listing expenses of \$0.3 million.

Loss from Change in Fair Value of Warrant Liability. The Company recorded a net loss of \$2.3 million in the six months ended June 30, 2017 for the change in fair value on revaluation of its warrant liability associated with the warrants issued in conjunction with its stock offering in February 2017. The Company is required to revalue certain of its 2017 warrants at the end of each reporting period and reflect in the statement of operations a gain or loss from the change in fair value of the warrant in the period in which the change occurred. We calculate the fair value of the warrants outstanding using the Black-Scholes and Monte Carlo Simulation models. A gain results principally from a decline in the Company's share price during the period and a loss results principally from an increase in the Company's share price.

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

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

Interest expense. Interest expense included expense accrued on our convertible promissory notes issued in 2015 and 2016 bearing interest at the rate of 8% per annum. These convertible promissory notes were all converted into common stock during the second quarter of 2017.

Net Loss. The net loss for the six months ended June 30, 2017 was \$3.75 million which included non-cash expenses of approximately \$2.6 million which included \$2.3 million for change in fair value of warrants liability and \$0.3 million for stock based compensation and depreciation.

Liquidity and Capital Resources. As of June 30, 2017, we had \$9.3 million in cash and cash equivalents compared to \$5.0 million at December 31, 2016. In February 2017, we completed a public offering of our common stock and warrants, pursuant to which we received approximately \$4.5 million in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. Additionally, through June 30, 2017, \$3.2 million in cash was received from the exercise of warrants issued in our February public offering. Cash used in operations was \$3.4 million for the period ending June 30, 2017. We believe that our existing cash and cash equivalents as of June 30, 2017 will be sufficient to fund our planned operations through the second quarter of 2018. Such plans are subject to change depending on clinical enrollment progress and use of drug product.

(Tables to follow)

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a preclinical stage pharmaceutical company focused on the development of anti-cancer drug candidates, some of which are based on discoveries made at M.D. Anderson Cancer Center. Our lead product candidate is Annamycin, an anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML. We also have two preclinical small molecule portfolios, one of which is focused on the modulation of hard-to-target tumor cell signaling mechanisms and the recruitment of the patient's own immune system. The other portfolio targets the metabolism of tumors.

For more information about the Company, please visit <http://www.moleculin.com>.

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, the Company achieving each of the milestones set forth above in the section entitled "Planned Activities and Upcoming Potential Milestones," the ability of Annamycin to show activity in patients with AML, the ability of Annamycin to qualify for accelerated approval, and whether WP1234 will become a drug candidate for the treatment of pancreatic cancer. These statements relate to future events, future expectations, plans and prospects. Although Moleculin Biotech believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Moleculin Biotech has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under Item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC") and updated from time to time in our Form 10-Q filings and in our other public filings with the SEC. Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

Contact

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Moleculin Biotech, Inc.
Balance Sheets
(in thousands except for par and share amounts)

	<u>June 30, 2017</u> <u>(Unaudited)</u>	<u>December 31, 2016</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,272	\$ 5,007
Prepaid expenses	809	215
Total current assets	<u>10,081</u>	<u>5,222</u>
Furniture and equipment, net of accumulated depreciation of \$14 and \$6, respectively	20	23
Intangible assets	11,148	11,148
Total assets	<u>\$ 21,249</u>	<u>\$ 16,393</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 645	\$ 1,069
Convertible notes payable	—	276
Warranty liability – current portion	1,185	—
Total current liabilities	<u>1,830</u>	<u>1,345</u>
Warrant liability	—	—
Long-term deferred compensation – related party	150	88
Total liabilities	<u>1,980</u>	<u>1,433</u>
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 75,000,000 shares authorized, 20,164,854 issued outstanding at June 30, 2017 and 12,164,852 issued and outstanding at December 31, 2016	21	12
Additional paid-in capital	27,711	19,623
Warrant receivable	(34)	-
Accumulated deficit	(8,429)	(4,675)
Total stockholders' equity	<u>19,269</u>	<u>14,960</u>
Total liabilities and stockholders' equity	<u>\$ 21,249</u>	<u>\$ 16,393</u>

Moleculin Biotech, Inc.
Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	515	105	1,199	120
General and administrative	800	618	1,649	923
Depreciation	5	1	8	1
Total operating expenses	<u>1,320</u>	<u>724</u>	<u>2,856</u>	<u>1,044</u>
Loss from operations	<u>(1,320)</u>	<u>(724)</u>	<u>(2,856)</u>	<u>(1,044)</u>
Other income (expense):				
Loss from change in fair value of warrant liability	(3,342)	—	(2,283)	—
Gain from settlement of liability	—	—	149	—
Gain from expiration of warrants	1,238	—	1,238	—
Other expense	—	—	(1)	—
Interest expense	—	(15)	(1)	(27)
Net loss	<u>\$ (3,424)</u>	<u>\$ (739)</u>	<u>\$ (3,754)</u>	<u>\$ (1,071)</u>
Net loss per common share – basic and diluted	<u>\$ (0.19)</u>	<u>\$ (0.08)</u>	<u>\$ (0.23)</u>	<u>\$ (0.14)</u>
Weighted average common shares outstanding – basic and diluted	<u>17,863,707</u>	<u>8,875,173</u>	<u>16,137,312</u>	<u>7,796,782</u>