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): NOVEMBER 13, 2018

MOLECULIN BIOTECH, INC.
(Exact Name of Registrant as Specified in its Charter)

DELAWARE	**001-37758**	**47-4671997**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File No.)	(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-14(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 [X]

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. [X]

Item 2.02 Results of Operations and Financial Condition.

On November 13, 2018, Moleculin Biotech, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2018 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release dated November 13, 2018

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: November 13, 2018

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated November 13, 2018

Exhibit 99.1

Moleculin Biotech, Inc. Reports Financial Results for the Third Quarter Ended September 30, 2018

HOUSTON - November 13, 2018 - Moleculin Biotech, Inc., (NASDAQ: MBRX) ("Moleculin" or the "Company"), a clinical stage pharmaceutical company focused 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 MD Anderson Cancer Center, today announced its financial results for the third quarter ended September 30, 2018. Additionally, the Company announced potential upcoming milestones and recent corporate developments.

Management Discussion

Walter Klemp, Chairman and CEO of Moleculin, said, “We maintain a sharp focus on the continuing development of our broad-based oncology portfolio and in effectively advancing those solutions through the FDA regulatory process. We have three core disruptive technologies and six oncology drug candidates that stoke our excitement with the possibilities for the treatment of rare and difficult cancers in the coming years. Recruitment for our Annamycin clinical trial in the U.S. continues; albeit somewhat slower than expected. Patient recruitment for our Annamycin clinical trial in the U.S. has been slowed due to a high number of competitive clinical trials currently being conducted, combined with the FDA’s requirement to set the initial dose level relatively low in comparison with previous Annamycin clinical trials. We will continue to work our way through this and complete the trial as diligently as possible. In Poland, we believe that patient recruitment for our clinical trial will proceed more expeditiously due to a comparatively lower number of competitive clinical trials taking place and the protocol there being approved to start at a significantly higher dose than in the U.S. with fewer enrollment screening limitations. We have multiple pathways to deliver our drug to Poland and we are making progress in that regard. Our expectation is to begin treating patients in Poland no later than the end of the first quarter of 2019.”

"We believe the opportunity for Annamycin is as strong as ever. We have made significant progress with our diverse and robust portfolio of technologies and we see great opportunities. Our immuno-stimulating STAT3 inhibitor WP1066 is now in a Phase 1 brain tumor trial at MD Anderson that is already showing positive progress related to bioavailability, and its water-soluble analog, WP1732, is in preparation for IND.We've made application for clinical trial authorization for another analog, WP1220, to treat Cutaneous T-Cell Lymphoma in Poland and we expect that trial to begin in early 2019. As our formulation work for our inhibitor of glycolysis molecule, WP1122, is nearing completion, we have just learned that new discoveries about immune checkpoint inhibition may also thrust this technology platform into the realm of immune therapy. The continuing progress in the development of our three diverse platforms and six drug candidates gives us increasing confidence that Moleculin will have 'multiple shots on goal' in successfully attacking certain rare and difficult cancers."

Recent milestones and accomplishments include:

- Enrollment has commenced for a physician-sponsored clinical trial of WP1066 for the treatment of glioblastoma and brain metastases in adults, and the first glioblastoma patients have received the initial doses of WP1066 in the physician-sponsored IND (investigational new drug) study at MD Anderson Cancer Center. Positive progress in the Phase 1 clinical trial of our immuno-stimulating STAT3 inhibitor, WP1066, was announced with initial results showing bioavailability of the drug in patients treated.
- Investigators at Emory University presented animal model data supporting the potential of WP1066 to treat pediatric brain tumors. The drug exhibits activity in those models against the most common form of childhood brain tumor, medulloblastoma, for which there is a desperate need for more effective treatments.
- Announcement of new data relating to WP1122 during IND-enabling research with animals that confirms a highly beneficial metabolism of WP1122 and significant organ accumulation of the inhibitor of glycolysis in the brain and the pancreas. We believe this is especially significant because both brain and pancreatic tumors are highly dependent upon glucose for survival and WP1122 appears to have the ability to inhibit glycolysis, the primary process by which these tumors convert glucose into energy.
- We have 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").
- We began preclinical toxicology testing of our WP1732, a fully water-soluble immuno-stimulating STAT3 inhibitor, through our new subsidiary in Australia, which provides aggressive incentives for research and development carried out in the country.

“We continue to move forward with great determination and drive; making consistent progress in the development of our three distinctly different technologies for the potential treatment of rare and difficult cancers. In addition, we are excited about the opportunity of using our drug candidates in combination therapies. We believe the characteristics of our three core technologies could be synergistic with one another providing even more opportunities in developing potential treatments for the rare and difficult to treat cancers we are targeting. We continue to emphasize that the Company has multiple shots on goal and we look to the future with great anticipation.”

Jonathan Foster, executive vice president and chief financial officer of Moleculin, stated, “The financial underpinnings of the Company are solid. We had cash of approximately $8.6 million as of the end of third quarter and access to capital in an equity line of approximately $20 million, which has not been tapped into to this point. We continue to carefully manage our operating expenses as we proceed along the drug development process. We expect that our Australian subsidiary will benefit not only from the generous tax credits in 2019 that Australia offers for R&D, but in the acceleration of the drug development process that these tax credits enable.”

Anticipated Milestones

Anticipated Milestone	Potential Timeframe
Initial IRB (Institutional Review Board) approvals and site initiations of various clinical sites participating in our Phase I/II clinical trial of Annamycin	**Accomplished** and ongoing through Second Half of 2018
Establishment of a new Recommended Phase 2 Dose for Annamycin	2019
Start treating patients in Annamycin Phase I/II clinical trial in Poland	Q1-2019
Announcement of initial clinical data for Annamycin trial	2019
Announcement of clinical data from WP1066 clinician sponsored trial	2019
Announcement of further benefits of our sponsored research agreement with MD Anderson	**Accomplished** and Ongoing into 2019
Announce filing and approval of CTA for WP1220 for the treatment of cutaneous T-cell lymphoma (CTCL)	2018 **(CTA Filed)**
Announce WP1122 move into preclinical work	2018
Announce WP1732 move into preclinical work	**Accomplished**
Announce IND for WP1732 submitted	First Half of 2019
Announce further research preclinical results on WP1066 family	First Half of 2019
Announce a fourth and fifth approved clinical trial	2019

Third Quarter Highlights and Recent Corporate Developments

Moleculin Announces Significant Milestone Achieved in Glioblastoma Trial - *WP1066 demonstrating drug bioavailability in on-going Phase 1 clinical trial* - November 01, 2018, the Company announced positive progress in the Phase 1 clinical trial of its immuno-stimulating STAT3 inhibitor, WP1066, with initial results showing bioavailability of the drug in patients. Although this data is preliminary, it represents a significant milestone for the development of WP1066. In the first two cohorts of the Phase 1 study, the Company saw measurable levels of the drug in the patient's plasma resulting from oral administration. The Company believes WP1066 is a first-in-class compound capable of stimulating a natural immune response in animal models while directly attacking tumors by modulating transcriptional activity and repressing what is called 'oncogenic transcription factors.' Chief among these is STAT3, considered a master regulator of tumor progression.

Moleculin Announces Positive Data on WP1066 in Pre-Clinical Trials - October 25, 2018, the Company announced that investigators at Emory University will present animal model data supporting the potential of WP1066 to treat pediatric brain tumors at the upcoming Society for Neuro-Oncology Annual Scientific Meeting held November 15-18, 2018 in New Orleans. The Company believes the data to be presented from Emory University will add to the enthusiasm for testing WP1066 in humans. What makes this particularly important is that the drug, WP1066, showed activity against the most common form of childhood brain

tumor, medulloblastoma, for which there is a desperate need for more effective treatments. The Company is proud to have two different Moleculin technologies, WP1066 and WP1122, being presented at this prestigious conference on brain tumors.

Moleculin Announces New Data Discovery Confirming Significant Increase in Potential to Starve Cancerous Tumors - *Data to be Presented at Neuro-Oncology Annual Scientific Meeting* - October 10, 2018, the Company announced that new data relating to its molecule WP1122 will be presented at the upcoming Society for Neuro-Oncology Annual Scientific Meeting being held November 15-18, 2018 in New Orleans. The discovery of new data of the inhibitor of glycolysis, WP1122, during IND-enabling research with animals confirms a highly beneficial metabolism of WP1122 and significant organ accumulation of the inhibitor of glycolysis in the brain and also in the pancreas. The Company believes this is especially significant because both brain and pancreatic tumors are highly dependent upon glucose for survival and WP1122 appears to have the ability to inhibit glycolysis, the process by which these tumors convert glucose into energy.

Moleculin's Brain Cancer Drug Candidate Begins Patient Dosing at Clinical Trial Being Conducted at MD Anderson -*Small molecule lead drug candidate blocks a critical target for tumors and crosses the blood brain barrier; begins first brain cancer patient dosing in a clinical trial at MD Anderson Cancer Center* - September 13, 2018, in the ongoing challenge to combat the almost always deadly brain cancers, namely glioblastoma and melanoma metastasized to the brain, the Company has initiated a Phase 1 clinical trial of a new first-in-class cancer drug candidate, a small molecule compound discovered by Prof. Waldemar Priebe at The University of Texas MD Anderson Cancer Center and known as WP1066. The compound has been shown in animal models to both inhibit an important cell signaling protein STAT3 that is involved in cell growth and proliferation and considered critical to tumor development, while also stimulating an immune response. The first glioblastoma patient has received the initial doses of WP1066, which were apparently well tolerated, in the physician-sponsored IND (investigational new drug) study at MD Anderson Cancer Center.

Moleculin Seeks Approval from Polish Regulatory Agency for Skin Cancer Clinical Trial -August 9, 2018, the Company announced its submission of a request to Polish authorities for a CTA for its STAT3 inhibitor, WP1220, for the treatment of CTCL which, if approved, will give the Company its third drug in clinic. Published research supports the belief that CTCL, a deadly form of skin cancer, may be highly dependent on the upregulation of the activated form of STAT3. The Company believes 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.

Moleculin Announces Enrollment Opens for Brain Tumor Trial of WP1066 - July 31, 2018, the Company 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, the Company believes that WP1066 may also have the potential to stimulate a natural anti-tumor immune response.

Moleculin Expects to Meet FDA IND Filing Requirements for its Pancreatic Cancer Drug Candidate with Development Work in Australia - July 18, 2018, the Company announced it began preclinical toxicology testing of its WP1732, a fully water-soluble STAT3 inhibitor with the potential to be a breakthrough discovery for rare and difficult to treat cancers, through its new subsidiary in Australia. By utilizing its subsidiary in Australia and the attractive R&D tax credits it offers, the Company believes it can accelerate the preclinical work of WP1732 and maintain a strong cash balance. The Company believes this will allow it to complete its IND-enabling work and meet FDA submission requirements before year-end, which should allow it to complete the IND filing during 2019, while also reducing the Company's total cost of development.

Moleculin Expands Operations to Australia; Taps R&D Incentive Program Capped at $20,000,000 AUD Turnover July 11, 2018, the Company announced it had formed Moleculin Australia Pty. Ltd., a wholly-owned subsidiary to oversee preclinical development in Australia. For companies like Moleculin with less than $20,000,000 AUD group turnover, it can amount to a rebate of up to 43.5% of qualified R&D expenditures.The Company believes its Australian subsidiary provides a great opportunity to speed up preclinical development and reduce the overall cost of continued drug development efforts.

Financial Results for the Third Quarter Ended September 30, 2018

Research and Development Expense. Research and development (R&D) expense was $1.3 million and $1.1 million for the three months ended September 30, 2018 and 2017, respectively. The increase of approximately $0.3 million mainly represents an increase of approximately: $0.2 million related to an increase in R&D associated headcount costs and $0.1 million providing clinical supply of Annamycin.

General and Administrative Expense. General and administrative expense was $1.2 million and $1.3 million for the three months ended September 30, 2018 and 2017, respectively. The decrease of approximately $0.1 million was mainly attributable to a decrease in investor relations expenses compared to the third quarter of 2017.

Net Loss. The net loss for the three months ended September 30, 2018 was $2.0 million, which included non-cash income of $0.6 million on the gain in fair value of our warrant liability, which was offset by noncash charges for $0.2 million related to stock-based compensation and other stock-based expenses.

Liquidity and Capital Resources

As of September 30, 2018, the Company had $8.6 million in cash and cash equivalents. On October 4, 2018, Moleculin entered into a purchase agreement ("LP Purchase Agreement") with Lincoln Park Capital Fund, LLC pursuant to which Lincoln Park has agreed to purchase from the Company up to an aggregate of $20.0 million worth of common stock. Under the terms and subject to the conditions of the LP Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $20.0 million worth of shares of common stock. Such sales will be subject to certain limitations, and may occur from time to time, at Moleculin's sole discretion, over the 36-month period commencing on October 30, 2018. To date, no shares of common stock have been sold to Lincoln Park pursuant to the LP Purchase Agreement. The Company issued to Lincoln Park 243,013 shares of common stock as commitment shares in consideration for entering into the LP Purchase Agreement and may issue an additional 121,507 shares pro-rata when and if Lincoln Park purchases (at the Company's discretion) the $20,000,000 aggregate commitment.

The Company believes that its existing cash and cash equivalents as of September 30, 2018 will be sufficient to fund its planned operations into the second quarter of 2019, without utilizing the LP Purchase Agreement. Such utilization of the LP Purchase Agreement should extend the funding of our planned operations significantly beyond the second quarter of 2019. Such plans are subject to our stock price and other limitations in the LP Purchase Agreement, change in planned expenses depending on clinical enrollment progress and use of drug product.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the development of oncology drug candidates, all of which are based on discoveries made at M.D. Anderson Cancer Center. 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 brain tumors, pancreatic cancer and AML. Moleculin Biotech is also engaged in preclinical development of additional drug candidates, including additional STAT3 inhibitors and compounds targeting 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 potential for Annamycin to demonstrate safety and efficacy in AML patients in clinical trials in the United States and in Poland, the timeframe in which such trials are completed and the ability to establish a new recommended Phase 2 dose for Annamycin during 2019; the ability of MD Anderson to successfully enroll patients in the Phase 1 clinical trial for WP1066, the timeframe in which such trial is completed, and the ability of WP1066 to show safety and efficacy in patients with glioblastoma or melanoma that has metastasized to the brain; the potential for WP1220 to become an effective treatment for CTCL and the ability of the Company to obtain Polish regulatory approvals to commence clinical trials to study WP1220 for CTCL; the ability and timeline pursuant to which the Company is able to prepare the preclinical data necessary for an IND for WP1732; the potential for WP1122 to become an effective treatment for brain tumors or the ability of a WP1220 analog to become a safe and effective drug for pancreatic cancer in humans; and whether Moleculin will be able to announce a fourth and fifth approved clinical trial during 2019. 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.

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---Financial tables on the following page---

Moleculin Biotech, Inc.

Unaudited Condensed Consolidated Balance Sheets

(in thousands)	September 30, 2018	December 31, 2017
Current Assets:		
Cash and cash equivalents	$ 8,600	$ 7,714
Prepaid expenses and other	760	588
Total current assets	9,360	8,302
Furniture and equipment, net	391	33
Intangible assets	11,148	11,148
Total Assets	$ 20,899	$ 19,483
Current Liabilities:		
Accounts payable and accrued expenses	$ 2,610	$ 1,712
Deferred compensation - related party	150	—
Warrant liability - current	369	503
Total current liabilities	3,129	2,215
Long-term deferred compensation - related party	—	150
Deferred rent - long term	92	—
Warrant liability - long term	2,710	—
Total Liabilities	5,931	2,365
Total Stockholders' Equity	14,968	17,118
Total Liabilities and Stockholders' Equity	20,899	19,483

Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share amounts)	2018	2017	2018	2017
Revenues	$ —	$ —	$ —	$ —
Operating Expenses:				
Research and development	1,332	1,061	6,801	2,260
General and Administrative and depreciation	1,259	1,343	3,886	3,000
Total operating expenses	2,591	2,404	10,687	5,260
Loss from operations	(2,591)	(2,404)	(10,687)	(5,260)
Other income (expense)				
Gain (loss) from change in fair value of warrant liability	573	(470)	1,614	(2,753)
Gain from settlement of liability	—	—	—	149
Gain from expiration of warrants	—	—	—	1,238
Other income (expense)	(21)	9	(23)	8
Interest income (expense), net	1	(1)	5	(2)
Net Loss	$ (2,038)	$ (2,866)	$ (9,091)	$ (6,620)
Net loss per common share - basic and diluted	$ (0.08)	$ (0.14)	$ (0.36)	$ (0.37)
Weighted average common shares outstanding - basic and diluted	26,861,497	20,534,720	25,373,634	17,683,441
Net Loss	$ (2,038)	$ (2,866)	$ (9,091)	$ (6,620)
Other comprehensive income (loss):				
Foreign currency translation	5	—	21	—
Comprehensive loss	$ (2,033)	$ (2,866)	$ (9,070)	$ (6,620)