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): DECEMBER 12, 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.)

5300 MEMORIAL DRIVE, SUITE 950, HOUSTON TX 77007
(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 7.01 Regulation FD Disclosure.

On December 12, 2018, Moleculin Biotech, Inc. (the "Company") held a live conference call. In connection with the call, the Company is furnishing the conference call script attached as Exhibit 99.1 hereto, which is incorporated by reference to this Item 7.01.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed to be "filed" for the purpose of the Securities Exchange Act of 1934, as amended ("Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated by reference.

Exhibit No.	**Description**
99.1	Conference call script dated December 12, 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: December 12, 2018

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Conference call script dated December 12, 2018

Moleculin

Exhibit 99.1

Call to Discuss Recent Breakthrough Discovery and FDA Filing on Wednesday, December 12, 2018

OPERATOR:
Welcome to Moleculin Biotech, Inc.’s Conference Call to provide a general corporate update and to discuss positive developments regarding the Company’s drug development pipeline. First - let me introduce Jonathan P. Foster, Executive Vice President and Chief Financial Officer.

JON FOSTER - EVP/CFO:
Thank you, Operator. Welcome everyone. Let me get some administrative matters out of the way.

First - we will have a discussion on the recent positive developments at the Company. Then we open the call for questions from our analysts covering our company, the professional investment community and with time permitting take a few questions that were submitted by email. Before we begin- let me read the following statement:

Some of the statements we make in this conference call 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 conference call include, without limitation, the ability of our drug candidates to continuing progressing toward an IND or an equivalent and, with regard to our drug candidates already in clinic, to continue progressing through the respective clinical plan cohorts and complete the planned trials without events. Although Moleculin Biotech believes that the expectations reflected in such forward-looking statements are reasonable as of today, 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 discussed in this conference call speak only as of today. We undertake no obligation to update any forward-looking statements contained in this call to reflect events or circumstances occurring after today or to reflect the occurrence of unanticipated events.

With that out of the way, let me introduce to you Moleculin's Chairman and Chief Executive Officer, Wally Klemp.

WALLY KLEMP - CEO & CHAIRMAN:
Good afternoon, and thanks for taking the time to join our Investor Update Call. Again, I'm Wally Klemp, Chairman and CEO of Moleculin Biotech, Inc. We'd like to use this call to give you a deeper insight into the importance of what has recently been discovered suggesting links between drugs in our portfolio and checkpoint inhibitors, as well as to update you on the status of all our programs.

Immune Checkpoint Opportunity

We've now made several announcements that begin to paint a picture of opportunity that is potentially much bigger for Moleculin than we previously thought. I'll recap those announcements for you, but first, I'd like to provide a little background on checkpoint inhibitors. As I do this, please bear in mind that, while we see great potential opportunity for Moleculin, much of the research is preliminary and not yet in humans, and we still have a way to go before submitting a new drug application to FDA, let alone having one approved. Much can happen between now and then, of course, but as we'll be discussing in a minute, we have reason to be optimistic and are prepared to do the hard work to keep moving forward and make the most of our opportunities.

The recent oncology drug landscape has been dominated by immunotherapy, specifically including checkpoint inhibitors. In just the last 5 years, checkpoint inhibitors (such as Opdivo and Keytruda) have reached over $10 billion in annual revenues. To put checkpoint blockade therapy into simple terms, the T-Cells within our own immune systems should be capable of identifying tumor cells and destroying them before they destroy us. Unfortunately, tumors develop the ability to prevent this natural immune response by regulating the expression of certain receptors referred to as "immune checkpoints" that then bind to T-Cells and prevent them from attacking the tumor. Immune checkpoint inhibitors are antibodies that block these receptor mechanisms and allow the T-Cells to act normally and attack the tumor.

When checkpoint inhibitors work, the results can be impressive, creating durable suppression of tumors where no other therapy had succeeded. This is the case, for example with metastatic melanoma. However, despite the outstanding results in select patients, checkpoint inhibitors only benefit a limited number of patients in certain cancers and they are essentially not effective in what are called "non-responsive" tumors like glioblastoma and pancreatic cancer, among others. As a result, companies are now focusing heavily on combination therapies, combining immune checkpoint inhibitors with chemotherapy, as well as other agents. There appears to be tremendous demand and we believe there is clearly a need for new chemotherapeutic agents that by their specific mechanism of action would produce potent combination effects with immune checkpoint inhibitors. And, we believe that some of our drugs used in this way may be poised to make a real difference here and could represent "home run" territory for a company like Moleculin.

Recently published research has presented several findings that in theory could suggest a major opportunity for Moleculin, and possibly more than one. One such article reveals that certain key transcription factors are responsible for the up regulation of an often-targeted checkpoint actor in tumors known as PD-L1. And, some of the most important transcription factors identified were HIF-1α, c-Myc and STAT3. Now, what is critical here is that we've shown in animal models that our drug, WP1066, can target these transcription factors very effectively. Based on these new discoveries, we believe administration of WP1066 could lead to improved treatment results in many patients receiving checkpoint inhibitor therapy.

Another recently published study focused on yet another new discovery helping to explain why some tumors are resistant to immune checkpoint therapy. The study found that a process known as glycosylation plays an important role the ability of checkpoint receptors to suppress immune activity and thereby protect tumors from attack. Beyond this, however, the researchers discovered that an alteration of the glycosylation of these receptor mechanisms could effectively prevent this evasion of the immune system. And, importantly, this study found that a substance known as 2-deoxyglucose, or 2-DG, was capable of making this alteration. These findings suggest that 2-DG could be beneficial as an anticancer agent in combination with checkpoint inhibitors and potentially with other anticancer therapies.

There is a problem with this approach in practice, however, because 2-DG has an extremely short circulation time as well as lacking other drug-like properties, so it doesn't stay in the system very long or concentrate in targeted organs, which severely limits its effectiveness. And, this is where our drug candidate, WP1122, comes in. WP1122 is what is known as a pro-drug of 2-DG, meaning it's a molecule that metabolizes into 2-DG, but that starts out with a slightly different structure. That structure gives WP1122 a longer circulation time and improved organ distribution, providing it a greater opportunity to become an effective drug. This could mean we have an ideal drug candidate to improve the performance of checkpoint inhibitors by reducing the effect of glycosylation.

I want to be careful not to get too bogged down in the detail here, so let me pull up for a moment and distill this into some summary comments. Even though checkpoint inhibitors are already a $10 billion a year business, they help only a small subset of cancer patients because of their limited efficacy. Recent discoveries are now pointing to the suspected culprits of this limited efficacy, and those culprits happen to include the very targets that several of our drugs are designed to hit. In theory, our drugs may be used to treat patients who are no longer responding to checkpoint inhibitors, allowing effective treatment for more patients, in more cancers.

Although these theories are compelling, it's actual data that matters. And, our sponsored research at MD Anderson is beginning to produce this data in animal studies combining WP1066 with checkpoint antibodies in tumor models. And, the results have been significant, with data suggesting that WP1066 may have the ability to improve the outcome of immune checkpoint therapy in tumors that are generally resistant to these therapies.

I need to stress that these results are preliminary, and we have now commissioned an independent lab to repeat these tests in their own animal models to verify this activity. As more results become available, this should represent additional important events for Moleculin to report in early 2019. Importantly, we believe with sufficient independent evidence, we may be in a position to attract collaborative investment from big pharma and we intend to begin that outreach in 2019. And, of course, since activity in animals does not necessarily equate to activity in humans, this outreach should be helped by the fact that WP1066 already has active Investigational New Drug (or IND) status, which is a prerequisite to clinical trials in human patients.

Update on Operations

Of course, Moleculin went public largely on the opportunity to get Annamycin into clinical trials for the treatment of acute myeloid leukemia or AML. Since then, a lot has happened in the AML space, but we believe our opportunity has only gotten bigger. The roll out of clinical trials of Annamycin has been hampered by a number of issues, but we finally see traction here and, in the meantime, the opportunity to apply our STAT3 inhibitor technology to the AML space gives us a wider range of opportunities to help AML patients.

Our US clinical trial for Annamycin has been slow to recruit, in part, because of the high number of competing AML clinical trials here and, in part, because of the FDA's request to start at a lower dose level than we would have recommended. We have now opened more clinical sites and have still more on the way, so we expect recruitment to accelerate in 2019. In Poland, our clinical sites have more available patients because of the low number of AML clinical trials there, but our ability to ship drug to Poland has been slowed by drug release documentation requirements in Europe that don't apply here in the US. As mentioned previously in our SEC filings - we have continued to answer inquiries and requests for additional information required for final approval by two different authorities - one in Europe and one in Poland - necessary to ship Annamycin drug product to Poland. We recently received the necessary approval in Poland and believe that we are close to finalizing with the European authority. So, we appear to have overcome these additional hurdles and expect to be announcing the treatment of patients in Poland soon.

As these trials have been unfolding for Annamycin, several new drugs have been approved in the AML space and it may be tempting for some to conclude that the opportunity for Annamycin is, therefore, diminished. We strongly disagree. The new drug approvals in AML have been based either on marginal improvements in overall survival or on significant improvements for a very small subset of AML patients. Critically, there remains no effective therapy for the vast majority of AML patients who will inevitably relapse from or be refractory to first line therapy, as well as recently approved new drugs. If anything, we believe the desperate need for more treatment options makes the opportunity for accelerated approval even greater for Annamycin.

Since our IPO, however, we have also gotten our STAT3 inhibitor, WP1066, into clinical trials via an investigator-initiated IND with MD Anderson Cancer Center and have recently announced pharmacokinetic data from that trial. That data demonstrated sufficient bioavailability of our

drug via oral administration to actually show the presence of WP1066 in blood plasma. To be clear, AML is often associated with a high upregulation of activated STAT3, referred to as p-STAT3. WP1066 is a potent inhibitor of p-STAT3 and our ability to get WP1066 into patients' bloodstreams suggests we could have a new way to combat AML, in addition to Annamycin. In collaboration with Dr. Jorge Cortes of MD Anderson Cancer Center, Professor Waldemar Priebe, our drug's inventor, has now been able to demonstrate activity of WP1066 against AML cell lines in vitro. So, the data now supports a move to get WP1066 into clinical studies for the treatment of AML.

The clinical trial that opened the door for WP1066 is now in full swing at MD Anderson Cancer Center. Investigators at MD Anderson have now dosed the 3rd cohort in a dose-escalation Phase 1 clinical trial for the treatment of brain tumors. And, that continued success is now helping to accelerate plans for another investigator-initiated trial, this time in pediatric brain tumors, at Emory University. You may recall that we recently announced that Emory researchers reported encouraging activity in their pediatric brain tumor models using WP1066, so they are extremely eager to get this trial started.

WP1066 is our flagship STAT3 inhibitor molecule. It has been the subject of over 50 peer-reviewed articles and its activity against p-STAT3 has now been validated in independent labs around the globe. And, while the MD Anderson brain tumor trial now supports bioavailability of WP1066 via oral administration, our desire to have alternate routes of administration for STAT3 inhibition drove us to also develop alternate STAT3 inhibitors that could be optimized for other delivery methods, such as topical and intravenously, or IV.

With regard to topical administration, our WP1220 is now awaiting approval for its first clinical trial in Poland for the topical treatment of cutaneous t-cell lymphoma, a potentially deadly form of skin cancer. And, the increased solubility of WP1732 represents, we believe, an opportunity to create a STAT3 inhibitor that is easily deliverable via IV. Independent animal studies now confirm that WP1732 can achieve a high concentration in the pancreas, suggesting that it may be an ideal candidate to be studied for treating pancreatic cancer. We have now completed its formulation development, and our IND-enabling toxicology work will be progressing via our Australian subsidiary, Moleculin Australia, and we expect to submit an IND in the US by mid-2019.

And, finally, our work continues on WP1122, our inhibitor of glycolysis, that research now suggests may be an important new way to increase the usefulness of checkpoint antibodies, as well as address highly glycolytic tumors like glioblastoma and pancreatic cancer. Formulation work on WP1122 is under way and although we expected to begin IND-enabling toxicology work before the end of this year, we now expect to announce the initiation of this work in the first half of 2019.

We now have six drug candidates and three active clinical trials, one of which is investigator-sponsored, with more trials expected in 2019. Our recent announcement of an Orphan Drug submission for WP1066 is just the first in a series of expected important regulatory moves to position our portfolio for successful development. Considering the potential news flow from Moleculin throughout 2019, we believe it's an ideal time to be following our company.

PAUSE

We have decided to open the call up to questions from the research analysts covering our company and answer questions submitted by our investors in advance of the call. So, let me begin with a question from one of our investors via email -

Q: One of our shareholders asked that we elaborate on the status of Annamycin.

A: Although I think I've done that in the prepared section of this call, I would add that we continue to work on increasing the visibility of Annamycin's potential within the hematology oncology community. To that end, we hosted a gathering of investigators from both the US and Poland at the most recent American Society of Hematology conference to discuss how important we think Annamycin could be for AML patients. Also, we will soon be announcing yet another high-profile AML expert joining our Science Advisory Board.

Operator we can now take questions from analysts covering our company:

(Take questions)

Other questions from investors via email -

Q: Glioblastoma is a very tough indication, what are your expectations for that trial?

A: We agree that going after GBM right out of the blocks is ambitious, especially since formulation and delivery may not have been optimized yet. For this reason, we definitely want to manage expectations. The first question was: "can we get WP1066 into the bloodstream via oral administration?" We now know that the answer to that is "yes." The next question will be whether we can reach sufficient drug concentration to actually affect biomarkers like p-STAT3 and TRegs. We should have a read on that in early 2019. If that turns out to be the case, a world of opportunity opens up for us. Now, if it actually has an effect on brain tumors, well we'll all be popping Champaign corks, but even if we don't see that in this trial, we have many ways to address improved drug delivery, and the range of opportunities with other tumors could be substantial.

Q: Would the Company be open to a joint development effort with one of the major checkpoint inhibitor makers?

A: The answer is "yes." In fact, we intend to seek this out, assuming the additional independent testing supports our early data. If it does, there will be a lot of follow-on work to do and it makes sense for us to collaborate with big pharma at that point.

Q: You guys have a lot on your plate; how are you managing to support all these programs?

A: For starters, we have expanded our organization over the last year, adding highly skilled operating people at the VP and manager level and the virtual organization we rely on easily doubles, maybe triples our size. As you know, we continue to access the markets for equity-based funding, but we also rely heavily on grant funding and investigator-sponsored activities. That said, we have more technology development potential in our portfolio than we have resources to pursue, so we continue to maintain a tight focus on the activities we think are most critical to providing new solutions for cancer patients and adding shareholder value.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical 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 clinical stage drugs are Annamycin, an anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML, and WP1066, a modulator of hard-to-target tumor cell signaling mechanisms intended to attack tumor activity directly while also recruiting the patient's own immune system. We are also engaged in preclinical development of additional drug candidates, including 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 ability of Annamycin, WP1066 and WP1220 to demonstrate safety and efficacy in clinical trials and the timing of the commencement of such trials, and the ability of WP1732 and WP1122 to achieve IND status and to demonstrate safety and efficacy in human patients. 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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