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): April 24, 2019

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 April 24, 2019, Moleculin Biotech, Inc. (the "Company") held a live conference call to discuss recent corporate events. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Conference call script dated April 24, 2019

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: April 29, 2019

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Conference call script dated April 24, 2019

Exhibit 99.1

Moleculin Biotech, Inc.,
General Corporate Update Call
Wednesday, April 24, 2019, 4:30 PM Eastern

CORPORATE PARTICIPANTS

Wally Klemp - *Chairman, Chief Executive Officer*

Jonathan P. Foster - *Executive Vice President, Chief Financial Officer*

PRESENTATION

Operator
Good afternoon and welcome to the Moleculin Biotech Inc's Conference Call to provide a general corporate update and to discuss recent developments regarding the company's drug development pipeline.

First, let me introduce Jonathan P. Foster, Executive Vice President and Chief Financial Officer.

Jonathan P. Foster
Great. Thank you, Jamie. Welcome everyone and I apologize for the delay. Let me get some administrative matters out of the way. We will have a discussion on the recent positive developments at the company. Then we will open the call for questions from our analysts covering the company. For questions submitted prior to this call by investors via email, Wally and I have tried to answer them in the body of our call. 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," "roughly," 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 with the Securities and Exchange Commission the 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 you to Moleculin's Chairman and Chief Executive Officer, Wally Klemp. Wally? I think Wally just got dropped operator?

Wally Klemp
I am back Jon - I just dialed back in.

Jonathan P. Foster
Okay, good deal. I just got done reading the forward-looking statement and you are right on cue.

Wally Klemp
Perfect, thanks a lot Jon. Hi, this is Wally Klemp, Chairman and CEO of Moleculin, and again I'd like to thank you for joining our conference call this evening. We've made a lot of headlines in the past few months with some very important developments. So, the purpose of this call is to pull this information together and make sure our shareholders and the investment community have a clear picture of what's been happening at the company and what we hope to see in the coming quarters.

The big news for us last week was, of course, the FDA approving Fast Track designation for Annamycin. We also announced pre-clinical data supporting the expansion of Annamycin indications to include lung cancer. All of these recent news releases appear to have given us the momentum and stock value to enable a $15 million registered direct offering that is expected to close tomorrow. This was a huge positive for Moleculin, and we believe it should be the last major financing we need before data readouts from our clinical activity later this year. We believe these developments could have a profound effect on the future value of Annamycin and therefore Moleculin, so we like to expand on these events to help ensure they are well understood. But first, let me give a general update on clinical activity for all of our programs.

This time last year we had just commenced our very first clinical trial, one drug, and one clinical trial. Now, we have three drugs in four clinical trials under way with a fifth clinical trial that may start before year end. We believe we have the potential to report meaningful data on a quarterly basis going forward. I'd like to summarize what's happening in each of these clinical trials to give you the clearest possible picture and help you calibrate expectations for the balance of the year

and into 2020. We believe that 2019 will be the year of data for Moleculin, as we report results from these ongoing clinical trials.

We now have two active Phase 1/2 clinical trials of Annamycin, one in the US and one in Poland. These trials have nearly identical protocols to treat adults with relapsed or refractory acute myeloid leukemia. Part of the reason there were two separate protocols is that the FDA wanted us to start at a lower initial dose level until we demonstrated the lack of cardiotoxicity that we expect for Annamycin.

We believe that the EMA was more focused on the unmet need of relapsed or refractory AML and allowed a higher initial dose and hopes to see efficacy sooner. We believe we've made good progress on both of these fronts, but the lower starting dose in the U.S. contributed to much slower recruitment here.

Although, it was valuable to determine that the starting dose in the U.S. of 100 milligrams per square meter did in fact have no cardio toxicity essentially clinicians here told us they were more reluctant to recommend their patients to this study until the dose level is closer to those levels that have shown therapeutic activity in previous trials.

In contrast, in Poland, where we were allowed to start at 120 milligrams per square meter, recruitment was much faster, in fact, we recruited as many patients in the first two months of the trial in Poland, as we did in the entire year in the U.S. And as we had hoped, we actually saw therapeutic effect in our first patient in the Polish trial at that higher dose level of 120 milligrams. After the first patient treated in that trial received a single course of Annamycin, his bone marrow blasts were reduced from 60% to 11%. Our principal investigator considers this response sufficient for the patient to proceed to consolidation therapy with the goal of receiving a potentially curative bone marrow transplant. Just as important to-date, there has been no evidence of cardio toxicity in any of the patients between the two trials.

The U.S. trial has now moved up to the 120 milligram per square meter level. So, we are optimistic that recruitment will pick up here. In Poland, we are close to advancing to the second cohort with the dosing level increasing to 150 milligrams per square meter, which was the dosing level in the prior developer's trial that produced responses in two-thirds of patients and completely cleared bone marrow blasts in one out of three patients. We've consistently stated that, if we can reproduce similar results in one of these current clinical trials, we should be able to qualify Annamycin for an accelerated approval pathway. And that's where Fast Track designation plays such a big role.

Fast Track is our first big step toward accelerated approval. In simple terms, we've laid out a proposal, a proposed approval pathway with the FDA and they've reviewed this proposal and concluded that Annamycin should be eligible for accelerated approval. The pathway we proposed was to complete the current clinical trial and if successful, run one more Phase 2b clinical trial designed for approval. This would allow us to have new drug approval before a Phase 3 clinical trial, which we would then conduct after approval as a confirmatory trial.

This potentially cuts years off of our development timeline, and also should make Annamycin attractive to development partners much sooner. But Fast Track represents more than just eligibility for accelerated approval. It also establishes a communication process with the FDA to continually look for opportunities to further streamline the regulatory process. This essentially gives us greater access to our review team at the FDA with more frequent calls and meetings and eventually leads

to what is called a rolling review of the new drug application whereby we don't have to wait to submit an NDA until all parts are completed.

I'm often asked what our best estimate is for new drug approval timing for Annamycin. Answering this requires so many assumptions that I must strongly caution investors to consider this to be a very rough estimate. With that said, I believe it's feasible for an NDA to be submitted by sometime in 2022. But we should know much sooner whether or not we are on track for such a positive outcome.

Remember, the prior developer of Annamycin saw what we consider to be the functional equivalent of 37% complete response in their last acute leukemia trial at 150 milligrams per square meter. But we believe we are seeing something close to that with the first cohort in Poland at just 120 milligrams. Now, individual cohort data is only preliminary and should not be considered an indicator of the ultimate outcome of the trial. But we expect to see more patient responses as dosing increases. And we are optimistic we can get the MTD above 150 milligrams this time around which may lead to even better outcomes.

The point is, we are now in a position for data to come out possibly on a quarterly basis going forward that will begin to paint a clearer picture of Annamycin capability and that, if positive, should put us in a position to begin more significant discussions with strategic partners. So, we don't necessarily have to wait until we are filing an NDA for value to be realized by Moleculin shareholders.

We also made another important announcement last week about Annamycin. We announced findings from our ongoing sponsored research at MD Anderson Cancer Center that Annamycin significantly increased survival in a mouse model for triple negative breast cancer metastasized to the lungs. Our development team considers this to be a very aggressive cancer. So, this was a surprising new discovery.

This, along with data from previous lung metastases models, is beginning to show what we believe is a promising pattern. Annamycin has been shown in certain of these models to accumulate in the lungs in quantities six-fold higher than the current standard-of-care anthracycline, doxorubicin, for example. And it's been shown to significantly outperform doxorubicin in two other lung cancer models. Now, keep in mind that doxorubicin, like all currently approved anthracyclines, is significantly cardiotoxic.

So, what does this lung data mean? Well, we believe its confirmation that Annamycin has significant opportunities beyond AML. Remember, if approved, Annamycin would be the first anthracycline available to patients that has little to no cardiotoxicity and that's why we call it a next generation anthracycline.

What this means in general, is that even if Annamycin is equally as effective as existing anthracyclines, it should become the first-line choice when anthracyclines are used, but in the case of lung cancer, and this is true for certain other tumors as well, the tissue/organ distribution characteristics of Annamycin are much better than say doxorubicin, suggesting it may have much greater efficacy, as well as greater safety.

We have focused on AML thus far, because a prior developer had already demonstrated a level of clinical activity that we believe would support new drug approval. We consider this to be the low hanging fruit, if you will. We are off to a great start with this approach, but it's still too early to tell. However, if approved, we believe the market potential for Annamycin goes way beyond AML

and we will be looking for opportunities to prove out some of that potential clinically as soon as possible.

In the meantime, we expect to fill out the 150 mg/m2 cohort in Poland before the end of the second quarter which means we could be reporting additional safety and efficacy data from this cohort early in the third quarter of this year.

One final note on the Annamycin front, we recently announced the addition of Dr. Martin Tallman, Chief of Leukemia for Memorial Sloan Kettering Cancer Center, to the company's Science Advisory Board. Dr. Tallman is considered one of the nation's leading experts in AML and we are honored to add Sloan Kettering to the distinguished list of institutions involved in making Annamycin successful.

What's happening with Annamycin is exciting, but, of course, Annamycin isn't our only clinical program. We also have two of our STAT3-inhibiting immune/transcription modulators in clinic. WP1066 is currently being delivered orally in a physician-sponsored brain tumor trial at MD Anderson Cancer Center. That trial is still in the dose escalation phase, but it has already shown that the drug is orally bioavailable, and we've seen no signs of toxicity so far.

We hope to be in a position to share data from this trial by the fourth quarter of this year. In the meantime, Emory University has signed an agreement with us to conduct another physician-sponsored clinical trial, this time in pediatric brain tumors also using WP1066. We hope to see this trial begin in the second half of this year.

Another molecule in this class of compounds is WP1220. This is formulated as a topical therapy and is now in a clinical trial in Poland for the treatment of cutaneous T-cell lymphoma. Our approach here was to get a quick proof-of-concept indication regarding efficacy. So, we plan to treat five patients and assess whether or not there's a basis to move to a larger trial. We've already recruited four patients and expect the fifth to be added within the next month. So, we should be in a good position to report preliminary data in the third quarter of this year.

We believe another major opportunity for this class of compounds is in treating pancreatic cancer. We recently announced the addition of Dr. James Abbruzzese, Chief of Oncology at Duke University to Moleculin's Science Advisory Board. Dr. Abbruzzese is recognized as one of the world's leading experts in the clinical study and treatment of pancreatic cancer. And he will be working with our team to design an appropriate clinical protocol for targeting this tumor type. We are also hopeful that our new partnership with WPD Pharmaceuticals may yield grant funding for this project.

With all of this clinical activity underway, we also continue to have additional drug candidates in preclinical development. We're advancing both WP1732, a water-soluble version of WP1066, and WP1122, our lead Metabolism/Glycosylation Inhibitor toward IND status.

Now, let me hand this call back over to Jon for a discussion on our financial status and on our recent equity raises.

Jonathan P. Foster
Thanks Wally. We will be reporting Q1 number soon. So I'm limited to speaking mainly from a year-end 2018 perspective, but I'll add some recent color. We ended 2018 with $7.1 million in cash on hand with our increased clinical and preclinical activity in 2018, which Wally just discussed,

and we also discussed in our recently filed Form 10-K. We doubled our R&D standard 2018 to over $9.5 million versus 2017.

I expect that our increased progress in R&D will necessitate an increase in overall R&D spend in 2019. I expect that increase to be roughly 20%. The level of increase depends greatly on the speed of recruitment and our clinical trials and the need for additional drug supply. The faster we progress in clinic, the higher our R&D expense goes. Our G&A costs are relatively fixed. As most of you are aware, we announced a $15 million capital raise yesterday. We were faced with unique market conditions at that moment where the price of the stock was at a point where we could raise capital on very favorable terms and we executed on it.

Having all the necessary components in place allowed us to be nimble and opportunistic. By way of background, we announced this call on Monday with the stated purpose of being able to discuss the significance of our prior week's news releases that we believed to have gotten lost in the holiday traffic. Just a few weeks ago, we raised $5.25 million at $1 per unit, we intended to raise more capital at that time, but market conditions simply wouldn't allow it. And it was clear that we'd have to raise additional capital in the future to allow our oncology drug development programs to continue uninterrupted through 2019 and well into 2020.

So given the opportunity presented to us by our investment bankers, just a few weeks later allowing us to raise an additional $15 million at a 60% price increase from the previous raise. There was no doubt that completing this offering was the responsible thing to do. We do not take these decisions lightly. We do these with the utmost care and the season advice of highly respected investment banks and counsel.

We view our primary responsibility to be the continued development of our potential cancer therapies for the benefit of patients and eventually our shareholders as well. It's important to note, we are a pre-revenue development company, and we will need to raise capital from time-to-time to advance our research programs.

We believe that increase in the strength of our balance sheet and mainly our cash position is the first step towards achieving our many important key milestones in 2019 and into 2020. We estimate that since the start at 2019 via warrant exercises and the issue of additional equity, including the offering announced yesterday, we have raised approximately $22 million in gross proceeds to fund our increase clinical activity.

With our current plans we estimate this funding will get us well into 2020. We now have the strongest balance sheet in the history of this company, which should put us in better position to begin shifting our focus to discussions with potential strategic partners as data becomes available over the coming quarters.

In fact, some initial conversations of this nature have already taken place, and as Wally mentioned, we believe it should be the last major financing we need before data readouts from our clinical trials become available later this year. The level of R&D expenditures planned should move Annamycin’s two clinical trials into the Phase II expansion cohort in 2020, announcing top line results upon each cohorts completion along the way, as well we planned to push WP1066 closer to the surgical expansion cohort with initial results been announced in the second half of 2019, and we expect initial top line results from our WP1220 trial on CTCL also in the second half of

2019. Our pre-clinical development should also result in an IND for WP1732 being filed by the end the year.

Finally, we continued to sponsor research with MD Anderson, and look forward to continuing to share exciting related developments later this year.

We believe all of these important milestones represent Moleculin's multiple shots on goal strategy. Wally

Wally Klemp
Thanks, Jon. We are extremely excited with the milestones achieved to this point and the ones coming up could be literally game-changing for us. We are highly focused on developing multiple shots on goal to attack highly resistant cancers, either in monotherapy applications or in combination drug therapies. And this last point is important in that we can potentially devise tailored combinations to address rare and difficult cancers from numerous angles and give hope to those who have exhausted currently available therapies.

We look forward to reporting successful clinical results as we continue to make progress developing our portfolio of oncology drugs. With this most recent financing in place, the potential to give patients more and better options to improve their quality of care is closer than ever. With that, let's shift gears here and I'll ask the operator to open the call up to questions from analysts.

QUESTION AND ANSWER

Operator
Ladies and gentlemen, at this time if an analyst covering the company would like to ask a question please press "*" and then "1", to withdraw your questions you may press "*" and "2." Again, that is "*" and then "1" to join the question queue. And our first question today comes from Jotin Marango, M.D., Ph.D. from Roth Capital. Please go ahead with your question.

Jotin Marango, M.D., Ph.D.
Hi, good afternoon, team, and congrats on all the progress.

Wally Kemp
Hi, Joti. Thanks.

Jotin Marango, M.D., Ph.D.
I have a few questions about Annamycin, first; I'm intrigued by the prospect of the Phase IIb for accelerated approval in acute leukemia. Could you give us a little more color on what this protocol could look like and specifically two points, what could be a control in the study. And then what type of end point, would be this disease progression or survival?

Wally Kemp
So, what's interesting here is the severity, the degree of the unmet needs here is extreme. And based on precedent set by other recently approved drugs, we can estimate what should be doable and it is just an estimate of course. But what we are thinking is possible here is essentially a single arm trial, monotherapy, with what we call surrogate endpoints. And Jaoti I know you know what that means, but for the benefit of the audience let me just explain that. Generally speaking, in trials like this, overall survival is a really important measure of endpoint efficacy in a trial, but it takes time to wait for patients to survive, frankly. And so, that kind of trial design can take a long time,

but in extreme situations where there is an immediate need for improved therapy, the FDA will allow the use of surrogate endpoints.

One of the most commonly used surrogate end points in this area is considered a CR, complete response and specifically that is primarily a reduction of bone marrow blasts to 5% or below as well as the restoration of certain level blood levels, but the heavy lift there is the reduction of bone marrow blast. And what that typically signals is the patient is now qualified for, or if they qualify as a good candidate for a bone marrow transplant, now they are qualified for that transplant and they have a really high probability of positive outcome.

So, it takes to summarize the answer to your question, Jaoti, we think that trial design here would probably be 65 to 75 patients and this would be single-armed monotherapy with surrogate end point of CR being the primary determining factor. And we used to think that we would probably need to show let's say 25% or 30% response, but we have now seen recent examples where certain therapies have been approved on even lower response rates than that. So, anyway that's our view of how this trial could be designed and executed of course subject to the FDA signing off on all those details.

Jotin Marango, M.D., Ph.D.
Thanks Wally. And thinking about the program what it is today, the parallel studies in the U.S., and in Poland. What level of data do you think you could have at hand and available for us to see by ASH. So I guess, conservatively what sort of an approximate number of cohorts or patients that you could have by now and how many of them are therapeutic level?

Wally Klemp
We continue to be a little bit gun-shy about making predictions in the U.S., regarding recruitment rate. Now that we have gotten up to 120 mgs**,** we are hopeful that recruitment will pick up but we need to see that to believe it. But by the way, that's why we also started the trial in Poland, as we wanted a backup plan and it turns out that our backup plan is working well because our recruitment rate is much better there.

So, then the next question is, when are going to reach the MTD? And, of course, the unanswerable question there is, what will it be? Right, because we go three patients at a time going from currently leaving the 120 cohort up to 150. The next level would be 180 level after that 210 and then even 240, if possible. The primary contributor to limiting dosing with Annamycin is expected to be mucositis. We don't have the cardiotoxicity problem that limits out doxorubicin or daunorubicin or other anthracyclines, but we do expect to limit out on grade 3 mucositis which is a nonpermanent condition, but nevertheless a serious condition, essentially, mouth sores and esophageal sores that make it painful if not impossible to swallow at least for the time being. Patients recover from that, but it is still considered a dose limiting toxicity if it becomes extreme.

So, in the prior developer's trial, the MTD was set at 150 milligrams, but those patients had no prophylactic treatment for mucositis and nowadays, we know that cryotherapy is an effective means to mitigate mucositis, and we are using that in the trial protocols here to try to coax the MTD higher than 150. So internally, our best estimate is that we think we are going to reach 180, possibly 210. And of course, the higher we go, the longer it takes to get to that end point where we can start saying here is the MTD, here is data and therefore, we can now move on to the expansion cohort.

With all that said, we feel fairly confident that we can get to 180 MIGS by the fourth quarter of this year. Now, if that turns out to produce some DLTs, then we would have to expand that cohort and then if the DLTs are confirmed then we would have to move back to the lower dosing level.

Having said that, I would say by fourth quarter we should have data to report from completed cohorts at 100, 120, 150 and 180, and if we are right about our expectations for Annamycin, and if prior developer activity is indicative, we should have a substantial number of CRs to report. That's why we are so excited about the data that we going to be reporting on a quarterly hopefully a quarterly basis, but essentially what would modulate that is when the cohorts are done, and we are committed to updating everybody as each cohort is finished.

Jotin Marango, M.D., Ph.D.
Thanks Wally. And then another question on the data on the findings that you reported last week, so the fact that Annamycin is now clinical gives a different type of significance to the findings in TNBC, because you couldn't [indiscernible] study. So perhaps, I am being too aggressive and forgive me if so, but what do you think you need to check off in order to move to a proof-of-concept there on the metastatic TNBC. So would you need additional pre-clinical data, [indiscernible] model or would you need to see more PKPD data from the hematology study. So what could be your progression assuming that you would want to move into a clinical state there?

Wally Klemp
Right, it is great question. And candidly, we think we now have enough preclinical data to present a rationale for lung metastases. I would like to emphasize because it is possible for some listeners to be confused by this. I would encourage people not to focus on TNBC or in this case Triple Negative Breast Cancer, but rather lung metastases. It just happens that that's one of the worst lung metastases you can have. But I just want to make it clear to people that we don't think that Annamycin is a good breast cancer candidate but rather metastases to the lung. Specifically, there is enough prior development activity to suggest that, and as well, Annamycin accumulates in the lungs, yet it doesn't accumulate well in breasts. So, it probably isn't a good breast cancer drug, but it could be an amazing lung cancer drug. And so, the reason we felt like that TNBC data was so significant is just how aggressive that model is. Our internal team basically said, look, we never see responses like this and we're seeing significant responses from Annamycin.

So that's all anecdotal and who knows whether that translates into humans, but we think there's enough to go on right now that I can tell you the team is already having discussions about writing protocols and putting forth a plan to senior management to say we'd like to add this to the list of things that we're going to go after. So, I think you're on it 100% right track. I don't think you're being too aggressive and I'm hopeful that later this year we're going to be talking about a protocol that moves beyond AML with Annamycin.

Jotin Marango, M.D., Ph.D.
Got it. And, I mean, we know from experience that M.D. Anderson is right. I understand the data is from they are known for supporting ISDs disproportionate compared to other centers. So has M.D. Anderson expressed any interest in the investigator study?

Wally Klemp
So, we haven't pursued that yet. Let's say we haven't pursued it formally. I can tell you that clinicians in lung at M.D. Anderson have informally said, we'd like to be a part of this, but I can also tell you a whole bunch of other institutions have said the same thing. And so, what I don't want to

do is leave the impression that it's automatically going to be an M.D. Anderson project. We're getting requests from a lot of respected institutions and so we want to make that choice based on how quickly we think we can move and what the relative costs may be involved and how interactive we think that the PI will be.

Jotin Marango, M.D., Ph.D.
Great. Thanks very much and congrats again.

Wally Klemp
Thanks, Joti.

Operator
Our next question comes from Naureen Quibria, Ph.D. from Maxim Group. Please go ahead with your question.

Naureen Quibria, Ph.D.
Hi. Good afternoon and congrats on the progress. So just piggybacking on the last set of questions on Annamycin, looking into other indications, particularly lung cancer, I was just wondering if you're looking into lung metastases or just lung cancer in general now that checkpoints are really used heavily in this indication, are you looking at Annamycin in combination with checkpoint.

Wally Klemp
So, it's a really good question because in this instance we considered that they could be complementary to one another. And so, the answer is yes, we are looking into those combinations as well as combinations with other drugs, but I can't talk about right now. But let me just put it this way: that the range of opportunities that we're looking at is pretty aggressive and of course even though we've raised a lot of money recently we still need to be very fiscally responsible. So, we're going to have to narrow this down now to say what are the things that are most likely to show positive responses. And so, we're working on that, but I think you're on the right track, Naureen.

Naureen Quibria, Ph.D.
Great. And that clarifies a lot. Just pivoting a little bit to one of your step, inhibitor programs the one in CTCL that, you know, that's I'm getting right now. Could you just discuss about the market opportunity there?

Wally Klemp
Sure. And I think Naureen, you probably know this, but it is a fairly rare disease, right, worldwide prevalence is below 50,000 and there are something like 8,000 to 9,000 reported cases a year, so it's not big. For reference, when you look at topicals that have been introduced to CTCL, Valchlor comes to mind and that was a drug that was acquired for almost $300 million once they got to approval. So even though it's a very small rare disease, it's not without the an important drug is not without value.

But what I would encourage people to consider is, that it really isn't just about the market opportunity for CTCL, but it's a great proof-of-concept for STAT3 inhibitors and showing a therapeutic response. I think if we show a positive response there, we theoretically would be making history showing a true STAT3 inhibitor delivering therapeutic response. There's a lot of enthusiasm around STAT3, but there haven't been a lot of clinical results where you can point to something and say we did that with a STAT3 inhibitor.

And this is one of those opportunities and I think once we do that notwithstanding the intrinsic value of CTCL, I think it also creates greater perceived value because strategics are going to look at that and say, okay, if they can do that with CTCL they can probably do it with a lot of other indications where STAT3 is up-regulated.

Naureen Quibria, Ph.D.
That's very helpful. That's it for me now. Thank you.

Wally Klemp
Thanks, Naureen, I appreciate that.

Operator
Ladies and gentlemen that appears to be the last of questions from analysts covering the company. And at this time, I'd like to turn the conference call back over to Wally for any closing remarks.

CONCLUSION

Wally Klemp
We definitely covered it. I appreciate everybody's time. There's a lot of work to do going forward and fortunately, now we've got the cash on hand to make sure that our plan can be executed without interruption. So, thanks again for your time this evening. And we look forward to further updates. Take care.

Operator
Ladies and gentlemen, that does conclude today's conference call. We thank you for attending. You may now disconnect your lines.