Matinas BioPharma Holdings, Inc.
Quarterly Earnings and Business Update
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Operator: Greetings, and welcome to the Matinas BioPharma Quarterly Earnings and Business Update Conference Call and Webcast.

At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please, press star-zero on your telephone keypad. As a reminder, this conference is being recorded.

I would now like to turn the conference over to Ms. Jenene Thomas, Investor Relations for Matinas. Thank you, Ms. Thomas. You may now begin.

Ms. Jenene Thomas: Thank you, Manny.

Good morning, everyone, and thank you for joining us this morning for the Matinas BioPharma Quarterly Business Update Conference Call. At this time, I would like to remind our listeners that remarks made during this call may state management's beliefs, hopes, intentions, expectations or projections of the future. These are forward-looking statements that involve risks and uncertainties. Forward-looking statements on this call are made pursuant to the Safe Harbor provisions of the federal securities laws. These forward-looking statements are based on Matinas BioPharma's current expectations and actual results could differ materially. As a result, you should not place undue reliance on any forward-looking statements.

Some of the factors that could cause actual results to differ materially from those contemplated by such forward-looking statements are discussed in the periodic reports Matinas BioPharma files with the Securities and Exchange Commission. These documents are available in the Investors section of the Company's website and on the Securities and Exchange Commission's website. We encourage you to review these documents carefully.

Following the Company's prepared remarks, the call will be opened up for a question-and-answer session. Joining me on the call today are Roelof Rongen, the Company's Co-Founder and CEO; Jerome Jabbour, Co-Founder and President; and Dr. Raphael Mannino, Chief Scientific Officer.

It is now my pleasure to turn the call over to Jerry Jabbour.

Mr. Jerry Jabbour: Thank you, Jenene, and good morning to everyone joining us for Matinas' second quarter 2017 results conference call. Toward the end of this morning's call, I will review our strong financial position and outlook for the balance of 2017 and 2018. However, our main purpose and focus this morning is to review and confirm our development program for our lead product MAT2203 toward an initial indication for the prophylaxis or prevention of invasive fungal infections in patients with acute lymphoblastic leukemia or ALL. Throughout this call, I will refer to this indication as "IFI prevention."

The second quarter of 2017 was truly monumental for our Company, our MAT2203 product and our overall delivery platform technology. This past June we announced data from two separate clinical trials of MAT2203 in the treatment of mucosal infections in two very different patient populations and at different dose and duration levels. Now, that we have had the opportunity to review the full available data set from each of these studies and discuss them in detail with numerous key opinion leaders as well as leading regulatory experts, we believe we have absolutely met our key objectives from these studies and are now positioned to engage with FDA with the goal of moving the MAT2203 development program into Phase 3 as quickly as possible.

Over the past six weeks we have spent a significant amount of time engaging with some of the world's leading experts in mycosis, all of whom we have been working closely with since 2015 and who were unanimous in their conviction that the data generated to date across all of our studies was compelling, validates the delivery mechanism of action of our drug delivery platform and warrants advancing MAT2203 into a pivotal registration study in IFI prevention as soon as possible, subject to the data to be generated and our already planned PK tolerability study in leukemia patients, the target patient population for our Phase 3 study. I will speak more about these experts and their role in our ongoing development program, as well as how we anticipate they might positively impact our expected FDA interaction a bit later on this call.

Before we look more closely at the data derived from these two important studies, let's take a step back and let me remind everybody about the uniqueness of our overall development program for MAT2203, which is based upon our unique ability to leverage our disruptive cochleate delivery drug platform, to transform the way an existing medicine already approved for the treatment of serious and life threatening fungal infections, amphotericin B, is designed and delivered.

Against the backdrop of increasing fungal resistance to available therapies, as well as the rising number of patients subjected to immunosuppressive therapy, which increases the risk of developing these deadly infections, our goal for MAT2203 has always been to give doctors and patients the opportunity to use amphotericin B, the most broad spectrum fungicidal agent in the battle against invasive fungal infections, in a safe and convenient way. The development of any antifungal drug is a different animal unto itself, but the development of an already existing compound in this area, in the unique direction we are seeking to take it while certainly presenting opportunities, also presents some interesting complexities as well. By complexities, I am referring to the reality in Phase 2 clinical trials, where in traditional drug development you are continuing to learn about your drug, things like specific dosing and dose regimens, and the data derived from these trials are often not viewed in the proper context. This can lead to misunderstanding and confusion about the existence or robustness of "positive data." Similarly, there is a natural, though inappropriate, tendency to want to compare results within indications or across studies simply because the same models were used, even if the respective

product candidates have very different development futures or target indications. This occurs because convention, especially in the antifungal area, dictates utilizing study models and designs which are not necessarily indicative of the ultimate development goals for a particular drug. More on that later.

Unlike most, if not all of the companies exploring novel antifungal therapies today, we began our program with a drug that we know and understand from clinical practice from an efficacy perspective is the go-to drug for the treatment of invasive fungal infections because of its broad spectrum activity and fungicidal nature. In fact, it is the ideal drug for immunocompromised patients for that very reason. We are also aware, however, of the legacy limitations on the historical use of amphotericin B because of its severe toxicity profile and inconvenient method of administration. But, because both clinicians and the FDA have a good understanding of the profile of amphotericin B from an efficacy perspective, our primary goal has always been to demonstrate that through our proprietary cochleate delivery platform technology we can orally and safely administer amphotericin B while achieving systemic delivery to infected tissues.

Following more than 20 consistent and positive preclinical studies in a variety of invasive fungal infections and in a number of different species, we, along with our key partner, the National Institutes of Health, set out to design a development program which would yield significant evidence of the safety and tolerability of MAT2203 along with efficacy representative of systemic absorption and distribution of drug to the site of infection. By necessity and for ethical reasons, early stage development work in humans for antifungal drugs must start with the treatment of less severe mucosal infections. It is well understood that an infection of the mucosal surface is essentially an overgrowth of an otherwise commensal organism. By commensal, I mean a situation where the fungi benefits without adversely affecting the host.

You see candida is present in all of our bodies. In that way, even with an infection of the mucosal surface, whether it is oral, esophageal or vaginal, the body does not necessarily see it as an infection. And so, it does not heavily recruit macrophage to cure or eradicate these types of infection. This is very different from invasive or deadly fungal infections, where macrophage are more activated and present. Unlike drugs that flood tissues, like fluconazole for example, our MAT2203 seeks to employ a more focused and targeted delivery to the site of infection, which in turn keeps serum levels of drug low, thereby elevating toxicity and increasing tissue absorption. In our ongoing trial with the NIH in immunocompromised patients with chronic mucocutaneous candidiasis, with the data from our first two patients, we successfully demonstrated the ability to safely and effectively treat patients who had suffered with these infections for decades. Most importantly, and at this point in time, two separate six-month extensions to this protocol have been granted. Meaning these patients have now been taking oral MAT2203 safely for more than eight months with exactly no signs of nephro- or other toxicities normally associated with the use of amphotericin.

Let's put that in context for a second. When you think about the period of time at which a normal or injected or liposomal amphotericin B starts to display signs of irreversible kidney damage or nephrotoxicity, it is typically between 10 to 14 days of use. In our NIH study we have two patients now that have been on the drug for 240 plus days with no toxicity. At the same time giving their underlying conditions and treatment history, they have each achieved dramatic improvements in clinical symptoms that were not previously achievable over decades with other therapies. This long-term, safe and efficacious use of orally delivered MAT2203 is absolutely unprecedented for amphotericin B and exactly the type of "wow" data that has the key opinion leaders so excited about the profile we are building for MAT2203 toward preventive use.

Our ability to utilize a broad spectrum fungicidal agent like amphotericin B for long treatment periods, while being well tolerated and safe, sets MAT2203 up for use as perhaps the ideal drug for prophylaxis, where, for example, the treatment periods will be approximately up to 90 days in patients with ALL. As you can see, we have moved to well more than double that treatment period with no evidence of toxicity. This key study remains ongoing as we continue to develop data on the safe long-term use of MAT2203, and we will continue to provide updates on this study as and when available and appropriate.

Our goal with the recently completed VVC study was to further establish the safety and tolerability profile of MAT2203, while demonstrating efficacy through a mechanism involving systemic absorption. Given limited study options because of ethical constraints, we chose VVC, as it provided a model to demonstrate oral and safe systemic delivery while allowing for efficient and expedient recruitment of patients. In other words, it would increase patient exposure and put us on a faster path toward a pivotal registration trial.

Our intention, and this has been consistently stated since before that trial began, was never to pursue an indication for the treatment of VVC. Because placebo-controlled trials are not conducted in this area for obvious reasons (i.e. no one signs up to potentially not be treated), we were left to utilize the standard of care in VVC, fluconazole, as an active control. However, according to the key clinicians and opinion leaders in this space, comparison to fluconazole is really of limited or no relevance given the ultimate development goals for MAT2203 in indications where fluconazole is contraindicated or inferior. Likewise, one cannot and should not compare the results of this study of MAT2203 in a VVC model to those of other drug candidates seeking an indication for the treatment of VVC. Similarly to fluconazole, those drug candidates today would either not be eligible or appropriate to pursue our initial indication for the prevention of invasive fungal infections in patients with ALL. For example, fluconazole, for as effective as it may be in the treatment of acute VVC, has a very limited spectrum of activity, is not at all effective on mold infections, and suffers from significant drug to drug interactions, especially in immunosuppressed patients.

So, as we began to receive additional data from this study, evaluate it in light of our overall development objectives for MAT2203, and discussed the same with the world's leading mycological experts, we have become more confident than ever in the profile of MAT2203, our overall data package that we have assembled to date and the readiness for this drug to enter a Phase 3 study in IFI prevention, pending completion of the planned PK tolerability study in leukemia patients that will commence later this year and continue for most of 2018.

Obviously, we continue to be extremely pleased with the safety and tolerability profile of MAT2203. We are also pleased with the evidence of efficacy demonstrated by a now thorough analysis of available data and discussions with our external team of clinical experts and advisors. In reviewing the disease severity scores from the recently completed VVC trial, we saw significant, meaning 80% reduction in severity attributes on Day 12. On the more stringent criterion of clinical cure, in both the modified intend to treat and per protocol populations, we saw rates of greater than 50% and a positive dose response affect between the 200 mg and 400 mg treatment groups. We believe this dose response affect also is demonstrated in the scores for eradication rate on Day 5, which was the last day of treatment for MAT2203 and being higher in the 400 mg treatment group than the 200 mg treatment group.

In our opinion, which is shared and informed by expert advisors, efficacy results like these, especially in a model not optimized either for amphotericin or for the way our MAT2203 is delivered, are highly encouraging, and when combined with the safety and tolerability profile we have built for this now orally bioavailable drug, we believe it positions us well to advance this much needed therapy into a pivotal trial in a patient population which today has no alternative and which remains vulnerable to developing a deadly fungal infection as a result at the alarming rate of 15 to 20%.

Following these two Phase 2 trials of MAT2203 our focus in the short-term is on two things. First, submitting a Type B meeting request to FDA for a meeting later this year to discuss our overall data package to date to highlight the data to be generated from our ongoing PK tolerability study in leukemia patients as the last phase of our Phase 2 and initiating discussions on our planned Phase 3 protocol. Second, ensuring that our PK tolerability study in leukemia patients gets off to a good start and positions us to begin receiving initial data from this important open-label study in the middle of 2018. Our QIDP and Fast Track status for MAT2203 provides us with great confidence that we will be granted a meeting with FDA this year. More frequent interactions with FDA was one of the key mandates of the GAIN Act.

In forming these two objectives is a world-class team of opinion leaders and experts, which includes Dr. Oliver Cornely from the University of Cologne in Germany, probably the world's leading expert on prevention of invasive fungal infections. Joining him is Dr. Dimitrios Kontoyiannis from MD Anderson Cancer Center in Houston, Texas, considered by many to be the world's leading expert in mycosis with over 500 peer review publications in this area.

These doctors are the key investigators in our PK tolerability study in leukemia patients at their request and will likely be for our Phase 3 program as well. Their experience with these types of patients that we desire to treat and their frustration with the current lack of available therapies is invaluable. We anticipate that one or both of them will also join us for our FDA interaction.

Our preparation of the necessary briefing materials for this FDA meeting is being supported by well-known former FDA reviewers in the infectious disease area, and they will also be present and likely lead our FDA interaction. It is the collective confidence of these experts, along with numerous others, including Dr. David Perlin, Dr. Peter Pappas, Dr. Jack Sobel and Dr. Edmund Tramont, who following a review of our current data package and development plan and objectives, are helping drive our momentum and focus toward the significant opportunity in IFI prevention and beyond. There is no question that there is a glaring unmet medical need, specifically in ALL patients where there is no current standard of care or treatment guidelines, and that MAT2203 in their opinion is poised to be the solution doctors and patients so desperately need.

In looking beyond our initial prevention indication, we have always envisioned pursing the treatment of a variety of invasive fungal infections as a way to broaden the commercial opportunity for MAT2203 and position it as a potential blockbuster drug. Importantly, and because of the timeline associated with our PK tolerability study of MAT2203 in leukemia patients, we will also take advantage of the significant interest shown by clinicians in the field of cryptococcal meningitis, notably Dr. Peter Williamson from the National Institutes of Health and Dr. David Boulware from the University of Minnesota, who approached Matinas to undertake clinical studies in patients with cryptococcal meningitis during 2018. We are already in the planning phase with the Intuitional Review Board at the University of Minnesota for this trial and expect to announce details on that protocol in the coming months. While we do not view these studies at this point as core or a prerequisite in any way to support moving into Phase 3 in IFI prevention, we believe these studies in cryptococcal meningitis will give us the opportunity to continue to broaden the utility platform for MAT2203 in the treatment of invasive fungal infections, while being supported by the interest of the leading clinicians in this area who today have little to no treatment options for their patients.

As we move into treatment trials in invasive fungal infections, we always want to be guided by promising preclinical data. As you likely recall earlier this year, we announced what has been characterized as extraordinary data from Dr. Peter Williamson's preclinical crypto models, which demonstrated dramatic improvement in the treatment of crypto by MAT2203 and the ability to be systemically absorbed following oral administration and successfully cross the blood brain barrier. A cumulation in infected brain tissues was demonstrated using rhodamine labeled fluorescent imaging. While these remain only animal studies, these promising preclinical data in one of the most stringent crypto preclinical models available gives us confidence as we prepare to treat patients with this deadly invasive infection.

So, as you can hear, we believe we are very well positioned to deliver potentially significant data and milestone events for MAT2203 over the next 12 to 18 months as we drive toward the commencement of our first Phase 3 trial. Our goal is to set up this potentially game changing product to become the gold standard and drug of choice for physicians looking to prevent and treat invasive fungal infections. If successful, the addressable markets would position MAT2203 to be a blockbuster drug.

We do not want to leave this call without also addressing the status of our MAT2501 development program. MAT2501 is our encochleated formulation of the broad spectrum aminoglycoside amikacin and is being developed initially for the treatment of non-tuberculous mycobacterium, an area of significant unmet medical need. As potentially the first ever-oral aminoglycoside, we believe MAT2501 has the potential to be a solution for a variety of chronic and acute bacterial infections, including gram-negative bacterial infections. We announced positive Phase 1 data from our single-ascending dose PK study in healthy volunteers earlier this year, which was highlighted by evidence of systemic absorption on top of an excellent safety profile.

Next, we will commence our multiple-ascending dose PK study of MAT2501 in healthy volunteers during the fourth quarter of this year. We determined to move into the second Phase 1 study as a way to build a broader foundation for MAT2501, which can then be developed for multiple indications without having to necessarily repeat early dose finding work. With the data from the multiple ascending dose study due in the second quarter of 2018, we believe we would be in a position to commence Phase 2 soon thereafter, driving this important product towards commercialization. From a commercial opportunity perspective, MAT2501 is being built and positioned toward a multibillion-dollar marketplace given its potential broad applicability, convenience of use and desirable side effect profile.

It really is an exciting time for our Company and these are just the first two products from what we believe could become a deep and robust product pipeline built upon our disruptive cochleate delivery platform technology. We continue to investigate the development of other compounds both on our own and in collaboration with third parties utilizing this delivery system, and it is our hope and plan over the next 12 to 18 months to be in a position to announce development programs in other very promising areas of significant unmet medical need.

Turning now to our financial results for the second quarter and our outlook moving forward, we ended the quarter with cash and cash equivalence of approximately $11.3 million. For the three months ending June 30, 2017, a net loss attributable to common stockholders of approximately $3.9 million or a net loss per share basic and diluted of $0.04. Importantly, we believe and anticipate that current cash on hand at June 30, 2017, as well as cash potentially available through our controlled equity offering sales agreement will be sufficient to meet our operating

obligations for at least a year and if fully utilized would finance the Company's operations through 2019.

In summary, we believe that the patient data announced by the Company during the second quarter of 2017 from most every standpoint relative to our development objectives: safety, tolerability and efficacy, positions us to advance MAT2203 toward a pivotal Phase 3 trial for an indication for the prevention of IFI in patients with ALL. Our development path is clear, and we will move swiftly and confidently toward an anticipated FDA meeting later this year as we aggressively continue to build a comprehensive overall data package for MAT2203, positioning it again to have the potential to be a blockbuster drug.

Our calendar over the next six, 12 and 18 months has the potential to be full of value creating milestone events, and we plan to sustain that momentum with our other key product MAT2501. We are extremely proud of the progress we have made so far during 2017, notably up-listing to a national securities exchange and delivering the first ever patient data utilizing our cochleate delivery technology platform.

We genuinely look forward to keeping our shareholders apprised as we continue to check boxes and hopefully build significant value in our Company. This will conclude our prepared remarks for this morning, and I would like to turn the call back over to the operator for our question-and-answer session.

Operator: Thank you. We will now be conducting a question-and-answer session. If you would like to ask a question, please, press star-one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star-two if you'd like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

Our first question is from Jason McCarthy of Maxim Group. Please go ahead.

Mr. Jason McCarthy: Good morning, guys. A couple of questions. First you had mentioned, going after mucosal infections first. It's just the pathway that you have to go through. What is the normal development pathway from mucosal infections to prophylaxis? And what I'm really asking is, why is the PK tolerability bridge so important? And, you know, how much data do you need to bridge to an indication in prophylaxis?

Mr. Jerry Jabbour: Great. Thanks, Jason. Thanks for joining us today. Um, you know, I'm going to ask Roelof to answer that question. He's designed the entire development program very purposefully to get us to this point today and really set us up to get to Phase 3. You know, as you properly mentioned, that bridge is really what's going to take us from where we are today to get into leukemia patients and it's an important one, but Roelof will handle that.

Mr. Roelof Rongen: Hey, good morning, Jason. Thank you. An excellent question.

When you develop a drug in the antifungal area, you're working in a rather difficult area because there are ethical dilemmas. And it's easy to see that if you have patients with an invasive fungal infection, at risk of dying, that you--in early stages, are cautioned by everyone involved: clinicians, the institutional review boards, to be very careful in how you treat these patients.

So, because of that ethical dilemma, the push has been to first go into mucosal disease. Mucosal fungal infections usually are not lethal. You know, they are clearly inconvenient and cause patients lots of trouble and, you know, do cause some long-term risks, but immediately, they are low risk and, therefore, a good starting point. And you will see that when you look at FDA summary basis of approval, summaries that--uh, that is a typical way to develop antifungal drugs. So there are numerous examples how that is typically the bridge to get started in the first patients and show efficacy.

Our bridge to the invasive fungal infection, prevention Phase 3 study, is the PK tolerability study in patients with leukemia and the reason we do this study is because we want to fully understand all the clinical issues of how a drug works in the ultimate target population of ALL patients, and understand how we can best dose, how high we can dose. That's where the tolerability aspect comes in. And in the end, you know, if there are patients enrolled that show altogether very quickly a very consistent picture then that becomes very crisp early on, and you might be able to take that to the FDA relatively quickly. If you have variability, if some patients show a different behavior rather than the other that's very important information because it tells you very important aspects of the drug, but then you have to accumulate a few more patients in order to kind of work to the point where you can draw conclusions.

So, that's in essence how we see that bridge. We want to make sure that we test our product in our target patient population for Phase 3. We do not want to have, you know, surprises at that point in time and we want to work, you know, carefully and deliberately to basically make that Phase 3 study a best way to get there with the lowest risk possible, the most thought through protocol, the best dosing regimen, so that is a homerun, you know, right from the get-go. That's what we're aiming for. So, that's where the tolerability study comes in. So, we think that the study can take, you know, the balance of most of next year, but maybe earlier if we can draw conclusions from a high level of consistency.

Mr. Jason McCarthy: Okay, great. And just building on that, how many patients for the leukemia study do you think you'd need? And I understand if it's open-label you can get some early data. Maybe that's enough for the FDA to get you to the Phase 3 study. But, I'm also looking at it as if you had enough patients and you really do have a 10 to 20% IFI rate, you know, theoretically you could get some infection prevention data at the end of that study. Is that fair?

Mr. Roelof Rongen: That is a possible way to look at that, and that's typically how we will look at that. Of course, it is an important aspect of the study. You know, the question is, what real comfort does that give you because there's always the issue are you lucky or unlucky in that respect? But, there are other parameters to look at.

And so, we can look at parameters of what is happening in the system of the patients. Can we count fungi and yeast in various body compartments? How is that affected? Is that likely to reduce the risk of the patient? How does that relate to the dose that we give the patient at that point in time? So, there are numerous other efficacy-like components that we believe we will gain from that study that will truly inform us on how to best design that Phase 3 study because there are many endpoints in the study. You want to show that you ultimately prevent these invasive fungal infections, but you also want to elucidate how, which patients are best targeted, are there other patient types that you need to give special consideration to, etc.

Leukemia is a complex condition and it's a life-threatening condition. So, you know, we try to understand the best modes of our product in that complex environment.

Mr. Jason McCarthy: Okay, great. And I just want to switch gears, if I could, for a sec. Over to the cryptococcal program. It was great data in the preclinical model. I know that this is separate from 2203 and IFI in prophylaxis. What is the clinical plan for the cryptococcal infections? I'm assuming that because you're getting blood/brain barrier crossing that these are brain infections as a result likely of patients with AIDS. Can you talk a little bit about that program and where you see that going over the next 12 months?

Mr. Roelof Rongen: Yeah. So, I think it's very important to note that, you know, as a Company we operate driven by the needs of the clinical community and that's true with ALL because the clinicians on the mycosis study group and many others have told us that that's where really the large need in the antifungal marketplace based on what the MAT2203 product is. But a product has numerous strength. This is born out of by, I think, a wealth of preclinical data, cryptococcal meningitis being one of them. And when the opinion leaders in that area knock on your door, like Peter Williamson at the NIH, produces fantastic results in what he considers a very stringent model of cryptococcal meningitis, then delivers results that are, you know, very-almost overwhelming in terms of, as you can see, the delivery of the drug to the mouse brain on a picture. You know, some pictures are worth a million dollars and this is one of them, I think.

Then other opinion leaders who have lots of patients in their clinics, and Dr. Boulware in the University of Minnesota is the key opinion leader. He has patients in his clinics throughout the world, including East Africa, that are dying everyday of this condition - it's a high unmet need area. And when he knocks on your door and says, "I really want to take your drug into this use and test it on my patients that are in high need. You know, IV amphotericin is not an option in

my field across the board. So, we need alternatives. Nothing else works," now, you're looking at an opportunity to help the patients, help the clinicians to serve these patients and help the product in development to develop a unique edge of efficacy. And, of course, you know, we're still developing that program. We're developing the protocol. So, we're at the beginnings of that. But, you know, this is a great way of showing the differentiation of MAT2203. It's rebuilding on the wealth of data in preclinical models with invasive fungal infections and that's really where the connection is, I think.

Mr. Jason McCarthy: Okay, great. Thanks for taking the questions, guys.

Mr. Jerry Jabbour: Thanks, Jason.

Operator: Thank you. The next question is from Robert LeBoyer of Aegis Capital. Please go ahead.

Mr. Robert LeBoyer: Good morning and thanks for taking my question. You gave a lot of good information about the 2203 program. The one question that I have is do you have any projection as to when the Phase 3 might start?

Mr. Jerry Jabbour: Yeah, Robert, thanks for joining the call today. A good question and a little bit of a moving target, right? And some of that is dependent certainly upon the interaction we'll have with FDA later this year, but when we look at, you know, the necessity of generating that data in the PK tolerability study in leukemia patients, we really view that as critical to really ensuring that we have a better chance of success in the Phase 3. So, we do want to wait and get a meaningful amount of data from that study, which will actually, to a large degree, help inform things like how we dose and how the protocol may be designed for Phase 3, but it's a little bit of a sliding scale.

And so, you know, obviously there's a certain number of patients we are targeting for the PK and tolerability trial. We currently project that it could take up to a year. But, as Roelof pointed out, depending on the consistency across patients early on in that study, there may be a meaningful amount of data or confidence we can generate from that, which will allow us to then go and have our interaction with FDA and go to Phase 3.

So, from a timeline standpoint, you know, we want to be conservative and realistic that there are still boxes we need to check before we go into Phase 3 and that the PK tolerability trial, if it goes the full duration, would last about approximately a year. So, that would put us in position for the beginning of 2019. But, we want to stress that because of the unique open-label nature of that PK tolerability study that timeline could be moved up. I think the most appropriate timing for us to really comment on detail on how we see all these pieces fit together is certainly after we've had an opportunity to have a positive interaction with FDA at the end of this year.

Mr. Robert LeBoyer: Okay, I agree with your plan to do the right amount of science before you get to Phase 3 rather than learning from Phase 3 what you should have done before that. But, okay--so, early 2019 would be an approximate guess at this point, based on what you're saying?

Mr. Jerry Jabbour: I think that's fair based upon our projected timeline for the PK tolerability study, but, again, you have to keep in mind the targeted indication we're going after, and when you're thinking about we are not going after a space on the map where there are alternative therapies or there are drugs that can be used today in this patient population.

So, when you think about targeting preventative treatment in ALL patients, you're talking about patients who today are not prophylax. They have no preventative treatment because of the drug-to-drug interaction with therapies that could be used, for example, in an AML population. And so, when you look at our development pathway and our timeline it's not what you would normally expect from a drug that's looking for efficacy for the first time or for safety data for the first time. You have to look at it in the context of: this is amphotericin B, which is well understood to have fungicidal activity. And us having demonstrated that it's orally bioavailable and now safe that gives us a leg up. And then, when you put in the backdrop of that the glaring unmet medical need in ALL patients and the support, really of the leading experts in the preventative treatment of invasive fungal infections, we think there's an opportunity to kind of advance things even quicker. But, we're always going to look at things through a conservative lens, but they have to be informed by the unmet medical need and the unique attributes of the product we're developing.

Mr. Robert LeBoyer: Okay, yeah, I understand that. You're breaking new ground scientifically and clinically, so you have to do things right even if it takes a little longer. Okay. Well, thank you very much for that.

Mr. Jerry Jabbour: Thank you, Robert.

Operator: Thank you. The next question is from Michael Higgins of ROTH Capital Partners. Please go ahead.

Mr. Michael Higgins: Good morning, guys, and congratulations on the progress during Q2. Thanks for the update this morning. A couple of questions, if I may. Any updates on the rCMC Phase 2A enrollment? When might we see more data from that? And is there an option that that could become pivotal via the LPAD pathway? Thanks.

Mr. Jerry Jabbour: Sure. You know, with respect to the NIH study, enrollment is ongoing, we continue to screen patients at a pretty high rate. That's a stringent protocol and so, ensuring that, one, patients fit within the parameters of the protocol as designed by the NIH. You remember these are patients with significant underlying health issues. And so, a lot of times

when we screen a patient they simply don't meet the criteria. In other words, they're too sick to be enrolled in the trial.

And the other aspect to that trial is that it's a pretty invasive protocol. They're asked to do a lot of things for a long period of time. That being said, you know, we know how important a third patient is in the scope of what a successful trial from a statistical standpoint would look like, meaning three out of 16 patients. It's our expectation, you know, that we'll be in a position to comment further on that this year, but enrollment continues and one of the important takeaways from that study is just continuing to demonstrate the long-term safe use of that drug in the existing patients who continue to have really impressive efficacy results as well. And so that trial's ongoing.

As far as LPAD, we continue to kind of investigate the potential to accelerate timelines based upon those more theoretical-than-actually-implemented kind of regulatory pathways. That is something that we regularly discuss with our regulatory experts and clinical experts, and may become part of what we discuss with the FDA as we head into this meeting in--you know, in the fall, but, again, focus is really important in those meetings, and our primary objective here is to, clear the pathway to get 2203 into a Phase 3 trial for IFI prevention. LPAD could present a unique opportunity for treatment indications earlier and it's certainly on our radar, but our focus is really clear in terms of IFI prevention at this point.

Mr. Michael Higgins: Okay, thanks. Regarding 2203's potential in the hemog indications, just want to clarify, are you targeting ALL patients only as indication in IFI prevention or other hemog indications and transplant indications?

Mr. Roelof Rongen: So, an excellent question, and this is truly a question about, you know, what is the optimal study design for Phase 3. And, as a company, we're very aware - we've looked at many companies doing non-inferiority studies, which are really the flavor du jour in the anti-infective space and the antifungal space. Those are very tricky studies.

And so we have now a unique opportunity in ALL only patients where because of the abundant use of vincristine, which is a core treatment for their leukemia condition the use of azoles is not possible. There are black box warnings in both azole and vincristine labels. So, you have a unique situation where ALL patients do not get prevention antifungal therapy. And with that they incur the risk and the potential lethal consequences of fungal infections because you basically take out their immune system and you start treating leukemia.

So now we have a unique opportunity to actually conduct a placebo-controlled trial because there is no standard of care. Placebo-controlled trials are usually very crisp usually require not the huge patient populations that you need in a non-inferiority study and that's probably going to be the quickest and best way to bring home the benefit of prevention in that population. So, that's one reason why we target that population as a core - the economics, if you think of why

does a company engage in this, well, ALL are compelling because the neutropenic period, the period in which your white cells, your immune system is down is, approximately three months, 90 days, as Jerry said before. And in AML, for instance, it's about, you know, 22 to 30 days is the typical window. So, it really is a lot more risk in terms of patient days there, which, you know, help to build the economic case. You can easily see that if a drug has proven to be successful in a core indication like ALL, you know, depending on the patient situation, the doctors have the liberty to take what they learn from our product in ALL to other patients.

So, even though that would be off-label and we would be not in any position to promote such use very clear, but the physicians in this field are very sophisticated. It's the same physicians that treat AML and ALL patients and deal with the stem cell transplant patients. So, once they become comfortable with a tool like MAT2203 for prevention in ALL, you can probably expect some spillover in these other uses of AML, stem cell transplant, maybe solid organ transplant.

And so, we believe that ALL is a perfect way to start. It gives us the best way to demonstrate, the utility of the drug and prevention in a concise, well defined patient population, but it also allows the physicians to then take that learning towards other patients that they serve.

Mr. Michael Higgins: Just a follow-up on that, what would be your current thoughts on expanding in the hemog area? Is it to wait for these Phase 2 results in ALL before moving forward or to do something while waiting for the trial to complete?

Mr. Jerry Jabbour: Well, in terms of, you know, waiting--I think waiting for that PK tolerability data in leukemia patients is essential. And so, I think before we kind of map out what area--what other areas within hemog we may pursue preventative indications, I think that data is very telling about how we will behave in that sort of immunosuppressed patient. It's not the be all and end all. And, remember, the PK tolerability study in leukemia patients will include both ALL patients and AML patients as a way to ensure faster enrollment. That's really, really important. But, as and when we get that data, and as and when we see exactly what the protocol for IFI prevention in ALL patients will look like, we are already evaluating and have spoken about our desire and the ability, we believe, of MAT2203 to become an answer in other immunosuppressed patients, all of which are orphan drug populations when you think about stem cell or solid organ transplant. Those also fit the criteria of the product model we're trying to build of 12 years of exclusivity and protecting all of those things.

Uh, and so--but we think we need to be able to stay focused in the short-term about developing this tolerability data in this patient population and at least getting the Phase 3 program in ALL prevention--in IFI prevention in ALL patients started. And then we will quickly highlight other areas, which we may want to investigate clinically so that you can round out your label as and when we're on the path to getting an approval for IFI prophylaxis in ALL patients.

Mr. Michael Higgins: Okay, that's very helpful. Thank you. Then just one last question, you discussed the safety of the two rCMC patients up to eight months. Can we get an update on the response rates in these and other patients? Thanks.

Mr. Roelof Rongen: Yeah, that's a very good question. So, we are very encouraged by the first two patients that NIH investigators reported on at the ASM Microbe last June. These patients continue to respond very well. They have to travel to the NIH on a monthly basis for their examinations and to get the next portion of drug that they take home. This continues to give them enormous quality of life improvements.

I think you heard Dr. Tramont talking about how one of the ladies in the study was able to eat pineapple again after two decades; the other lady able to eat her favorite southwestern spicy food. So, you know, that remains very important, and at the same time, you know, we are able to see that, uh, safety picture, the tolerability picture for, you know, the kidney function, for liver function and other aspects kind of build up to a very meaningful timeframe that is now a multiple of our target of 90 day.

And so, this kind of a spearhead group of patients that really is going to be very informative. And to continue to see the patient respond well, not see any resistance develop, which is kind of expected from amphotericin, but it's good to see that in our study, those are very key components. And so, we are very encouraged and very happy with those two patients.

Mr. Jerry Jabbour: And just to add some color to that, Michael, you know, when you think about these extension periods, these patients are continuing to take that highest tolerable dose at which they saw a response and as we talked about with those first two patients, both really came into this study with a severity score of around seven, and Patient 1, you know, improved down to the three, four level, which was a 57% response, and Patient 2 went from a seven to a one, which was an 85% response, or as Dr. Tramont commented on during the NIH's presentation of the data essentially cure because there was skin or no growth during that time period.

Interestingly, you know, with the first patient there was a period of time where she had to come off the drug and the candida level rose back up to a significant amount. That's also pretty helpful in understanding that once you're not taking our drug, especially in these immunocompromised patients, the candida returns and the disease returned to a higher level. Once the patient went back on the drug, she returned down to the lower level again and even were informed that we're still waiting for the most recent data has even improved beyond 57%. For Patient 2, the most recent data we've seen is that we know she went from a seven to one. We know that she's been essentially upgraded to a zero.

So, that is really, really good evidence that we're continuing to have in patients who are susceptible to continuing to contract these infections that at minimum we're in great

maintenance mode of the improvements we've made already and that on balance we are also starting to see with long-term use continued improvement and that's the other aspect of why we want this to continue is we want to see how these patients perform not only from a safety perspective but from an efficacy perspective.

So, on both fronts, safety and efficacy, we continue to be real--I mean not only us, but really Dr. Tramont and Dr. Freeman, the doctors who have treated these patients for such a long period of time, continue to be really excited about what they see. And that's really the impetus for continuing to grant extensions. You're not going to continue to grant six-month extensions simply to give patients a drug that's not effective, even if it's safe you're not going to continue to just give people these drugs. There's no placebo affect when somebody is a Job's patient or is genetically immunocompromised. So, the drug is really working.

Mr. Michael Higgins: Very helpful. Appreciate the color. Thanks, guys.

Operator: Thank you. There are no further questions at this time and with that, ladies and gentlemen, this does conclude today's teleconference. You may disconnect your lines at this time. Thank you for your participation and have a wonderful day.