Provectus Biopharmaceuticals Conference Call - August 7, 2014 4:00 p.m. EDT

Operator: Greetings and welcome to the Provectus Biopharmaceuticals First Quarter Conference Call.

At this time, all participants are in a listen-only mode. A brief question and answer session will follow the formal presentation.

If anyone should require operator assistance during the conference, please push star, zero on your telephone keypad.

As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Michael J. Porter, President of LeVay & Rose.

Thank you, Mr. Porter. You may begin.

Mr. Michael Porter: Thank you, Adam, and good afternoon, ladies and gentlemen.

On the call today are Peter Culpepper, who is COO and CFO; and Dr. Eric Wachter, the CTO of Provectus.

Before we start the conference call, though, please note that some of the information you're hearing today during our discussion will consist of forward-looking statements as defined under the Federal, uh, Securities Law.

These statements reflect management's current knowledge, assumptions, belief, estimates, and expectation, and express management's current views of future performance, results, and trends.

Actual results could differ materially from such forward-looking statements.

For more information, please refer to the risk factor discussed in Provectus's 10-K for 2013, the Form 10-Q for the Second Quarter of 2014, and Provectus's other filings with the Securities and Exchange Commission.

Provectus assumes no obligation to update any forward-looking statements or information which speaks to their respective dates.

No claims with respect to PV-10 are intended regarding safety or efficacy in the context of the forward-statements contained in these statements.

I'd like now to turn the call over to Peter Culpepper, CFO and COO.

Good afternoon, Pete.

Mr. Peter Culpepper: Thank you, Mike, and welcome, everyone.

Today's conference call is part of our continued policy of clear communication with our shareholders.

We will hold regular conference calls timed to coincide with the filing of our 10-Q or 10-K, the case may be, to allow for greater interaction between the company and its shareholders.

We believe that this will help avoid unsubstantiated gossip from damaging our financial interest and create a better atmosphere for investment.

For today, we'd like to address a few points that Mike and his company have encountered in managing our investor communications.

In no particular order, they are our cash position and financial capacity to complete our clinical trials, activities in China and India, the hiring of an FDA advisor, the roles of our advisory committees, the status of our Phase 3 protocol for PVT-10 as a melanoma treatment, and an update on the status of our other research projects.

After that, we will gladly answer questions on these or any other subjects you wish.

Our cash and cash equivalents were $18,126,036 at June 30, 2014 compared to--compared with $15,696,243 at December 31, 2013.

The increase of approximately 2.4 million was due primarily to 4.35 million cash received from warrant [sp] and stock option exercises and 4.35 million net proceed from the sale of our common stock and private offerings in the six months ended June 30, 2014, offset by 6.3 million of operating cash expenses.

Now, wearing my hat of CFO, let me be crystal clear. We have enough money on hand this minute to see us through to the interim Phase 3 data for the melanoma study.

I believe that by managing variable cash expenses, due to minimal fixed cost, our cash and cash equivalence are sufficient to meet our current and planned operating needs now until 2016.

We can curtail or defer certain expenditures and we will do so. This means we do not anticipate needing to raise additional capital to further develop PV-10 on our own between locally advanced cutaneous melanoma, cancers of the liver, recurrent breast cancer, pancreatic cancer, and other indications.

Why do I say that? Because we plan to strategically monetize PV-10 through appropriate regional license transactions and to license PH-10 for psoriasis and other related indications described as inflammatory dermatoses.

We discussed this strategy in our filing today, the Q-2 10-Q MD&A, particularly the liquidity in capital resources section.

And how can we be so confident those regional licensing deals will happen?

We believe our efforts to obtain regulatory clarity will be helpful to facilitate such transactions with potential partners.

Additionally, the existing and forthcoming clinical and non-clinical mechanism of action data for both PV-10 and PH-10 are expected to further aid of both regulatory clarity and transactions with potential partners.

Also, management is returning 8.96 million to the company as a result of the previously announced settlement of a shareholder derivative lawsuit subject to a two for one credit to the executives, such as the total actuary payment by the executives may be a 1.12 million for executives, which would total 4.48 million.

Now, that brings us to activities in India and China.

We have provided data on a confidential basis to both potential global and geographic partners for both PV-10 for oncology and PH-10 dermatology via a secure electronic data room.

We are encouraged by the number of companies doing due diligence on our technologies.

For instance, we recently had a team in India meeting with potential partners. And these Indian pharmaceutical firms are continuing their research into our data; they are regular visitors to our data room. Additionally, we are having discussions on possible commercialization.

Also, we have two teams focused in China working with potential partners there. And discussions on working with these Chinese businesses continue.

The Chinese talks involve both melanoma and liver indications, the latter being a more widespread problem than China.

We also have begun to consider co-development transactions with one or more pharmaceutical or biotech companies to combine PV-10 with immunology agents, such as those referred to as checkpoint protein inhibitors.

While none of these has yielded a concrete result that I--that we can report to you, I am comfortable mentioning these activities because I'm confident they will do so eventually, meaning potentially even this year.

At this stage, I will hand the floor to Eric Wachter, our Chief Technology Officer, for discussion of FDA related matters.

Eric?

Dr. Eric Wachter: Thank you, Pete.

Uh, I want to start out my remarks by emphasizing that our primary focus is on managing the FDA regulatory process.

Provectus is contemplating adding to its consulting advisors a group to help us validate our efforts with the agency.

This group is a full-service regulatory consulting firm that provides strategic guidance to companies, like Provectus, regulated by the Food and Drug Administration at developing innovative solutions to pressing public health challenges around the globe.

Under the terms of the contemplated agreement, this consultant will have several duties.

They will review all of the correspondence between Provectus and the FDA. They will provide an overview of potential drug regulatory pathways for PV-10. They will review and analyze the FDA's breakthrough therapy designation program to see what more can be gleaned from what we went through earlier this year.

This group will review and analyze our developed program for PV-10, highlighting things like our proposed indication, mechanism of action, primary and secondary influence selected for clinical studies, pivotal study designs, and available Phase 2 data.

They'll analyze the current landscape for marketed and emerging products for melanoma and compare PV-10 to the current pair standard for melanoma.

They will summarize their analysis of our PV-10 development program and key regulatory challenges and opportunities.

In essence, they will aid us in validating the relevance of the PV-10 drug development program in all material aspects for the treatment of serious or life threatening diseases or conditions, such as locally advanced cutaneous melanoma.

This comprehensive third party review will identify our strengths, allowing us to build on those, and our weaknesses, allowing us to address those.

We have a very unique product in PV-10 and as the inventor and chief proponent of our drug, we have developed unique expertise related to the unique challenges of establishing safety and efficacy sufficiently to support regulatory approval.

This consultant relationship will allow us to see how our approach compares to standard industry practice and help us to identify those areas where we can improve our execution.

We don't expect this process to drastically change our course, but rather to verify that we are on the right course and make small corrections necessarily to ensure that we are successful in reaching our goals.

I think that the efforts of this advisor group duck tail very well with the function and expertise of our strategic advisory board.

As many of you know, our advisors take an active role in helping Provectus.

For example, Craig Eagle, a senior VP with Pfizer Oncology is a co-inventor on our joint patent application with Pfizer, covering certain uses of PV-10 in combination with systemic therapies.

Bob McGlone [sp], a medical advocacy and external medical affairs advisor, has played an instrumental role in advancing our efforts to establish global and geographic partnerships for both PV-10 for oncology and PH-10 for dermatology.

And Joe Kalil [sp], associate director of health science executives of Bering Ingelheim [sp] has been very instrumental in advancing our efforts to establish key partnerships for PV-10, in particular, across Asia.

Let's turn now to the status of the protocol for our Phase 3 study of PV-10 for melanoma.

This study will access response to intralesional PV-10 versus that of systemic chemotherapy in patients with disease confined to cutaneous and subcutaneous sites.

These patients will have failed or be ineligible for systemic immunotherapy and must have extremely limited options, consisting principally of systemic chemotherapy, such a DTI [unintelligible] or a clinical trial.

As we've indicated previously, the primary end point of the study is progression free survival assessed using standard criteria.

Secondary endpoints are complete response rate and overall survival.

Progression free survival and overall survival are standard endpoints for oncology approvals.

With these assessment methods and endpoints, we're following what the FDA has suggested to document the clinical benefit to patients after intralesional injection.

Furthermore, our endpoint of complete response rate should allow us to highlight one of the key features of PV-10 and we'll measure patient reported outcomes to better characterize the relationship between complete response and symptoms of locally advanced continuous melanoma, such as pain and bleeding.

We're working with several leading CROs with specialized expertise in the assessment of patient reported outcomes to show that our planned assessments are rock solid.

This is an important, but complex topic and the experience of these expert groups is allowing us to put into place the final missing pieces of our protocol.

We've indicated previously that we plan to commence the study this year and this work is allowing us to put the finishing touches on the protocol before it undergoes final review in the next few weeks by key melanoma investigators and consultants in clinical operations and regulatory affairs.

So, to summarize so far, we are finalizing the process of combining our expertise gleaned from years of clinical testing of PV-10, input from meetings with our scientific advisors, investigators, and advocates in the field, and design input from multiple [unintelligible] having specialized expertise in key areas, such as assessment of patient reported outcomes, radiologic and clinical image management, biostatistics, clinical data management and so on to ensure that we a robust protocol that can address the needs of licensure.

We are also adapting to the extent possible important design elements from successful pivotal trials of other drugs recently approved in melanoma and other cancers that address issues pertinent to pivotal testing of PV-10.

These include details on scheduling of response assessments, handling of issues pertinent to our comparative drugs, and the collection and interpretation of patient reported outcome.

While the study design process is being wrapped up, I'd like to note that our prior guidance on design of the study remains unchanged with approximately 210 patients needed for the study and two to one randomization.

We use a dosing scheme based on our current expanded access protocol, which was updated about a month ago incorporating all that we've learned since we began our melanoma program.

To hit the ground running, we expect to start enrolling patients at our existing PV-10 sites in the United States and Australia, which are currently enrolling melanoma patients into our expand access protocol. And then add additional sites in these two countries while we expand to additional sites in other parts of the world.

Our initial focus on the United States and Australia will allow us to leverage almost a decade of clinical experience working with leading investigators in these countries. And that together represent a very substantial fraction of the global population of melanoma patients.

As we finalize preparation for launching the study, we expect to add a few additional centers to our expand access program, allowing us to establish the local operational

contractual and regulatory framework for rapid transition of these centers to participation in the Phase 3 study.

We're also adding a number of closely held consultants and CRAs, or clinical research associates, who will play important roles in management of this trial as well as our other ongoing and future studies.

As is standard in our industry for Phase 3 where team management of study operations in data collection and analysis, will be handled by a full service interactional CRO with expertise in clinical operations and integrated data management.

This key member of our team, our quarterback as it were, will coordinate the global efforts of the study team, including that of our investigators as well as an independent review--as well as independent review committees analyzing study data and an independent clinical trial data monitoring committee, or DMC, that will periodically review the accumulating data to ensure that our study provides patients with maximum possible safety while protecting the scientific validity and the integrity of the data we gather.

These preparations, and the fact that we're closely following precedent of recent successful pivotal trials in melanoma and other cancers, as well as the advice of the agency in the fundamental design of our study are intended to be sure to the full extent possible that we have a successful trial.

As Pete mentioned earlier, we're also looking beyond single agent therapy with PV-10 to address the needs of patients with more extensive disease, particularly those with visceral tumors that are not injectable.

One track--one attractive and complementary approach that may be to combine PV-10 with a systemic immunotherapy, such as immune checkpoint protein inhibitor.

Immune checkpoint protein inhibitors, such as anti-CTLA-4, anti-PD-1, and anti-PD-L1 agents are an important advance in the treatment of melanoma and other cancers, and are the subject of intent development in our industry.

However, while these drugs represent an important step forward, like any drug, they're not perfect and they might be improved.

As was clearly presented by the medical oncology community earlier this summer as ASCO, using an agent like PV-10 to prime the immune system could be synergistic in combination with such a systemic agent.

Our patent application on this strategy was published in 2012 and we've been vigorously pursuing this approach since.

The non-clinical research we presented at the society for immunotherapy of cancer annual meeting in 2012, together with ongoing translational clinical research on PV-10's

mechanism of action that we're sponsoring at Moffitt Cancer Center and our own Phase 2 data provide a rationale for combination testing of PV-10.

This development track separate from the Phase 3 study I discussed earlier could represent a path forward for patients with significant disease burden not amenable to intralesional injection and is a possible candidate for co-development with one or more pharmaceutical or biotech companies.

So, to reiterate, we expect to commence the Phase 3 melanoma study by the end of the year, including filing the protocol with the agency and starting patient enrollment at sites already using PV-10 under our expand access protocol.

Moving from melanoma, I want to discuss what we're doing with PV-10 METAcancers along with the development with PV--PH-10 for skin conditions.

We've recently expanded our exploratory Phase 1 study of cancers of the liver to three centers; St. Luke's University Health Network in Bethlehem, Pennsylvania; and the Southeastern Center for Digestive Disorders and Pancreatic Cancer in Tampa, Florida; in addition to Sharp Memorial Hospital in San Diego, California.

And we're evaluating addition--several additional centers to further advance this study.

We've been working with our investors to report results from long term follow up of our initial patients at one or more conferences and in the literature in coming months.

And we're assessing strategies to accelerate transition to Phase 2 testing in randomized control trial either alone or in combination with systemic therapy.

Any combination studies in liver are likely to follow similar development strategies to those outlined, uh, earlier for melanoma and rely on much of the same foundational science.

The current Phase 1 study initially intended only to establish safety of percutaneous injection of PV-10 into liver tumors. That is, injection of the tumor through the skin. It is providing valuable safety and efficacy data crucial for planning such Phase 2 development.

This trial is open to patients with hepatocellular carcinoma or other cancers that metastasize with liver who have at least one tumor that is either originated in or spread to the liver.

All patients receive the same treatment; an interventional radiologist injects PV-10 percutaneously into a single liver tumor.

Patients with multiple injectable tumors may later receive further PV-10 to their other tumors.

In addition to comprehensive [unintelligible] monitoring, we're assessing both the short and long term effects on injected lesions and any effects on uninjected lesions in the patient's liver.

We've received numerous inquiries about the study from researchers as well as patients and their doctors and we refer these to our investigators through the contact information available on the clinicaltrials.gov website.

As we continue to learn more about the effects of PV-10 on both HCC and other metastatic cancers, the data on non-HCC tumors may shape plans for future indications.

And as Pete mentioned at the start of the call, given the well known public health prices posed by HCC and parts of Asia, what we're learning in this study may have direct bearing on potential partnerships in China.

Between our studies in melanoma, hepatocellular carcinoma, and other cancers, metastatic liver, and breast carcinoma, well over 240 patients have received PV-10 since we started clinical work with our first patients in Australia.

Over 200 of these are melanoma patients representing the 100 patients who participated in our Phase 1 and Phase 2 melanoma trials and over 100 melanoma patients have been enrolled under our expanded access protocol since then.

These numbers are based on our 2013 annual report to the agency and we will update these totals later in the year as we prepare our 2014 annual report.

While we're encouraged by the sustained enrollment of patients by our investigators, I'll note that this demand illustrates the need for new options for cancer patients.

We expect to greatly increase these numbers in the coming months as we continue to build our case in support of initial approval of PV-10 and in support of extending approval through additional indications.

And finally, just a quick update on PH-10, our lead investigational drug candidate for dermatology.

So far, over 220 patients have participated in Phase 1 and 2 trials of PH-10. We anticipate posting results from these studies on the clinicaltrials.gov website in the coming months and are encouraged by what we've observed to date.

Trialing the model we've successfully used in oncology, we've designed a translational clinical study to better understand the possible immunologic mechanism of PH-10 in the skin.

This mechanism of action study will focus on the suspected cellular and structural changes in psoriatic plaque upon treatment with PH-10.

We've observed structural changes since our first trial of PH-10 in psoriasis and clinical observations from subsequent studies point to a possible immunologic response to PH-10.

Looking in concordance of clinical changes with any changes observed inside the skin should provide insight into this apparent response.

We've designed the study with thorough input from several leading experts on the immunology of psoriasis.

We've completed non-clinical validation of the concept to ensure that PH-10, which is pink in color, does not interfere with immunologic testing to skin samples from study participants.

And we've used our previous psoriasis studies as a template for the operational aspects of this study.

We expect to conduct the majority of the clinical work at major academic centers in the United States to ensure the integrity of the results to be generated.

The knowledge we expect to gain from this study should enable us to design advanced trials in psoriasis, eczema, and other inflammatory dermatoses and potentially differentiate product among the range of options for these conditions.

Well, that covers the material that we wanted to discuss so far, Mike.

Uh, so, I think it's time for questions.

Mr. Michael Porter: Uh, thanks, Eric.

Uh, before we turn the call over to the operator, I've had a number of calls today about one question everybody would like to know and that is why is it taking so long to start the official Phase 3 trial?

Dr. Eric Wachter: Uh, okay, Mike.

As I outlined in my earlier comments, we're working to address both long term and recent guidance from the agency. And in particular, the recent guides provided our interactions with the agencies since December concerning the relevance of symptom assessment in our patient population. Those patients with locally advanced cutaneous melanoma.

We're working with leading partners in this area to finalize this aspect of our study design and expect to send our protocol out for review by our team of CROs, regulatory consultants, and investigators in coming weeks.

We have the significant advantage that when this process is complete, we can access existing relationships with our investigators to accelerate progress.

We also have clinical drug supply on hand and a distribution system that have been tested to ensure that PV-10 is available when the first patients are enrolled.

Mr. Michael Porter: Thank you, Eric.

Uh, Operator, we're ready for questions.

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 would like to remove your question from the queue.

For participants using a speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

One moment while we poll for questions.

Our next question comes from the line of Max Asenheimer [sp], who is a private investor.

Please proceed with your question.

Mr. Max Asenheimer: Hi, gentlemen.

Mr. Peter Culpepper: Yes. Hello, Max.

Are you there, Max?

Operator: Thank you.

Our next question comes from the line of Bruce Bissell [sp], who is a private investor.

Mr. Bruce Bissell: Good afternoon, gentlemen. Uh, this is Bruce.

Mr. Peter Culpepper: Good afternoon, Bruce.

Mr. Bruce Bissell: Yeah. My question, uh, about Phase 3 trials.

First off, I want--can you--Eric, can you be more specific about the lessons learned in Phase 2?

Are we going to dose patients differently than earlier? Or can you talk about that a little bit?

Dr. Eric Wachter: Uh, sure, Bruce.

So, um, as we've progressed from Phase 1 to Phase 2 and now on the threshold of starting Phase 3, uh, we have progressively, uh, dosed patients more aggressively based on what we've learned from those prior studies.

Uh, for example, Phase 1, we treated patients once. A single course of injection.

Uh, in Phase 2, we waited eight weeks before we retreated patients.

Um, in our recent past in our expand access program, we waited four weeks between possible injections and we've recently amended that to allow, uh, treatment every two weeks.

Uh, we'll apply those learning, uh, experiences certainly to the Phase 3 study.

Mr. Bruce Bissell: Okay. Do you see then a--or two remaining questions.

Do you see a potential for better results in Phase 3?

And second, exactly what will the FDA's role with the protocol be? Will you simply file the protocol with the FDA? Or do they have some other--some advanced role in that?

Dr. Eric Wachter: Okay. I can't really speculate on, uh, what effect size we anticipate seeing in Phase 3. Classically, there's a fragment that is effect size of compression and, uh, the, uh, effective drug is smaller progressing from Phase 1 to Phase 2 and then again from Phase 2 to Phase 3.

We've seen the opposite so far going from Phase 1 to Phase 2. Uh, I don't know if that is necessarily going to be a continuing trend, but it's certainly, uh, is directionally favorable.

Um, we will be using, uh, fully, uh, conforming resist assessments in the, uh, Phase 3 study versus modified resist assessments.

So, it really is not directed comparable.

Having said, we do expect to see a very high rate of complete response consistent with, uh, patients in the Phase 2 study where we treated all existing disease.

We'll be treating all existing disease in our Phase 3 patients. And so, we can use that group from Phase 2 as a model.

Uh, in terms of the agency's requirements, we are required to file the protocol with the agency prior to commencement of the study.

Um, I can't comment on any further activities we might have with the agency in that regard.

Mr. Bruce Bissell: Thank you.

Operator: Thank you.

Our next question comes from the line of--the next question comes from the line of Bill Hemming [sp].

Please proceed with your question.

Mr. Bruce Binso: Hi, guys.

Dr. Eric Wachter: Hi, Bill.

Mr. Bruce Binso: I don't know if you just sort of answered this and I missed, but, um, is there a certain timeframe once you actually submit the process or the plan, the trial design to the FDA?

Is that, uh--is there then a certain amount of time before it starts? Is it a definitive amount of time? Do they have 60 days, 30 days? Or is it an automatic, uh, once you're in--once you've applied, if you don't get a no, you can go forward?

Dr. Eric Wachter: Uh, there's a 30 day, uh, wait that's required when you submit a Phase 1 study, uh, particularly the first Phase 1 study, uh, for an indication.

Uh, subsequent studies at, uh, progressive phases, uh, there is no mandatory wait prior to commencement of study.

That being said, uh, the agency has the, uh, option to comment, uh, or take other action on a protocol at any time after it has been submitted.

So, uh, in terms of commencing a Phase 3 study, the requirement is that we submit the protocol prior to commencement of the study.

Mr. Bruce Bissell: Okay. So, then you would submit it and then you would give places like Ogawala [sp] the green light to go forward?

Dr. Eric Wachter: That's correct.

Uh, they would have to pursue, uh, IRB approval that does not have to occur after submission to the agency. You simply have to have the IRB approval and submission to the agency in place prior to starting enrollment.

Mr. Bruce Bissell: Okay, great. Thank you.

Operator: Thank you.

Our next question comes from the line of Bruce Binso, who is a private investor.

Please proceed with your question.

Mr. Bruce Binso: Well, I guess I'm in here for two questions then.

Uh, uh, there--there's been confusion--this is a Peter question. There's been confusion in terms of cash flow, whether, uh, to include the 4.48 portion of the settlement or the 8.96.

Uh, in terms of somebody projecting out cash flows, which is more relevant, uh--which is a better estimate of the impact on cash.

Mr. Peter Culpepper: Uh, thank you, Bruce.

For cash forecasting purposes, I would use the 4.48.

The settlement as we disclose is for 8.96 million. So, that's the gross amount. But, it is subject to the two for one credit, given certain conditions.

So, conservatively, I used the 4.48, uh, in forecasting because that presumes that we will meet the terms and then have the two for one credit.

So, that's--that would be my response, Bruce.

Mr. Bruce Binso: Thank you, Peter.

Mr. Peter Culpepper: Sure.

Operator: Thank you.

Our next call comes from Dr. Gullem [sp], who's a private investor.

Please proceed with your question.

Dr. Gullem: Thanks for taking my call.

I have two questions.

Uh, one, uh, before a licensing deal can be inked, would it be necessary to have an acceptable protocol with the FDA?

Mr. Peter Culpepper: Thank you, Dr. Gullem, for that question.

This is a gray topic and we are actively discussing with potential partners in both India and China, in particular, when to enter into a transaction.

But, I think conservatively, it does make sense for protocol for both melanoma and liver that's appropriate for those respective countries to be in place prior to at least a transaction be consummated. It's possible that MOU could be signed in advance.

But, conservatively, I think it makes sense for, say, you, as an investor, Dr. Gullem, or any to see that protocol filed on clinicaltrials.gov and then you could make the logical, uh, assumption from there. Once we saved dates with melanoma study or the Phase 2 liver that Eric touched on has been filed, that that makes sense for potential, uh, global--or, uh, geographic partners.

Eric has a comment.

Dr. Eric Wachter: And as the CTI cover both, uh, clinical development and intellectual property portfolio of the company and I'll point out that in those sorts of scenarios, uh, it's almost certain that any protocol will be entered into--in Asia would be an international protocol, uh, because of certain, uh, implications of a single country protocol and intellectual property rights.

So, um, you can expect that that would be one of the aspects of such a protocol.

Dr. Gullem: Okay. Um, the second question I have, uh, we're facing, uh, a share price below a dollar. And, uh, I just would like to know if you, uh, uh, expect or looking to take some type of action to avoid, uh, the potential delisting threat that looms over us?

Mr. Peter Culpepper: Yeah. Thank you, Dr. Gullem.

Obviously, we're very optimistic about our future, short-term as in this year. And I call to your attention in the MD&A of the 10-Q filed today in the liquidity of capital resources section, fourth paragraph, in particular, that we believe our financial position and corporate governance are such that we will continue to meet the relevant listing requirements of New York Exchange MKT, although there can be no assurance that we will continue to be listed.

But, what we're doing is we're making sure that the financial position in corporate governance are appropriate to enable the share price to appreciate or to facilitate that it is exactly what we're doing with the clinical trial activities and what that means to the market, and to potential transactions with, uh, uh, partners.

So, I would argue that we're doing what we need to do on all fronts to ensure that we continue to be listed.

Dr. Gullem: Thank you, gentlemen. I have a lot of faith and confidence in you.

Mr. Peter Culpepper: Thank you.

Dr. Gullem: Carry on.

Mr. Peter Culpepper: Thank you. We appreciate your, uh, comment.

Dr. Gullem: Bye-bye.

Operator: Thank you.

Our next question comes from the line of Max Asenheimer who's a private investor.

Please proceed with your question.

Mr. Max Asenheimer: Hi, gentlemen. I got cut off before. I don't know what happened.

Dr. Eric Wachter: Yeah. Sorry, Max. But, welcome back.

Mr. Max Asenheimer: Well, I was under the assumption from last conference call that, um, Phase 1, uh, uh, for liver was going to be out soon. Am I wrong in that?

Dr. Eric Wachter: Uh, I don't think we indicated that the Phase 1 data would be out soon. We indicated that we were working to get that data available to the public.

Um, we have been working since the last call and since we've, uh, issued the shareholder letter, uh, a month and a half or so ago to advance that process.

And I can't say that we have made, uh, great progress in that, um, but, the process of preparing those sorts of, uh, materials for dissemination through either the purity of literature or, uh, through technical conferences has a fairly substantial lead-time.

So, we can't, uh, tell you right now where that is, um, and we can't tell you exactly when that's going to happen. But, I will assure you that we're moving that forward.

Mr. Max Asenheimer: Do you think it'll happen before the end of the year?

Dr. Eric Wachter: Uh, that's possible.

There are, uh, a number of conferences that are, uh, in the fourth quarter that we are looking at, uh, and it depends upon whether we're able to get our data into shape in time for submission to those in advance of their deadlines.

Mr. Max Asenheimer: All right. One last quick one.

Um, when you mention interim results on the Phase 3, uh, what kind of general timeframe are you looking? Sometime towards late 2015, mid 2015?

Dr. Eric Wachter: Uh, so, we have, uh, previously stated that we expect that, uh, accrual for the study will require approximately 18 months with an additional 12 months follow up for the last patient.

Uh, interim assessment would be, uh, roughly at half way point in that study. Um, and so it would be somewhere on the order of 15 months after commencement of the study. So, sometime, uh, at the end of 2015 or early in 2016, presumably.

Mr. Max Asenheimer: All right.

Well, thank you very much. I appreciate it.

Dr. Eric Wachter: Thank you.

Operator: Thank you, gentlemen.

There are no further questions at this time.

I would like to turn the floor back over to management for your closing comments.

Mr. Michael Porter: Uh, everyone, I want to thank you all for attending our conference.

Uh, we will talk to you next quarter.

Um, have a good Labor Day weekend.

Thank you very much.

Goodbye now.