Provectus Biopharmaceuticals
Third Quarter 2014 Quarterly Business Update
November 6, 2014

Operator: Greetings and welcome to the Provectus Biopharmaceuticals Third Quarter Investor Update 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 press star, zero on your telephone keypad.

As a reminder, this conference is being recorded.

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

Thank you, Mr. Porter. You may begin.

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

On the call today with me are Peter Culpepper, who is Chief Operating Officer and CFO; and Dr. Eric Wachter, the Chief Technical Officer of Provectus.

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

These statements reflect management's current knowledge, assumptions, belief, estimates, and expectation, and express management's current view 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, quarterly filings this year, including the Form 10-Q for the Third Quarter of 2014, and Provectus's other filings with the Securities and Exchange Commission.

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

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

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

Hi, Pete.

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

Today's conference call continues our practice this year of clear and comprehensive communication with our shareholders in this form of transparency.

We commit to hold regular conference calls, timed to coincide with the filing of our 10-Qs and 10-Ks to allow for greater interaction between the company and stockholders.

We believe that this will ensure the opportunity for all to hear from management and then participate and hear the questions that are asked along with the company response.

At 4:00 p.m. eastern time today, we issued a press release announcing that we filed with the FDA our Phase 3 Protocol for the use of PV-10 to treat melanoma. This follows closely on the heels of the completion of the due diligence audit by INC Research of our regulatory documents for PV-10 and PH-10 for purposes of ensuring we're responsive to the FDA.

INC Research has reported that all regulatory documents relating to PV-10 and PH-10 are indeed in order and we are ready to in fact move forward with our Phase 3.

Today's press released announced that we've submitted a Phase 3 Protocol for evaluation of PV-10 for treatment of locally advanced cutaneous melanoma to the FDA.

The FDA is expected to review this admission and comment on the proposed study population, clinical endpoints, and statistical analyses within 30 to 45 days.

Provectus believes details of the protocols will be available publicly on clinictrials.gov within the next few days.

The submission of the protocol follows completion of the due diligence audit of Provectus' regulatory documents for PV-10 and PH-10. The purpose of the audit was to ensure that all the regulatory documents were in order.

Provectus anticipates few, if any, significant issues to arise from review of the protocol based on the substantive contact it has had with the FDA since the company had its Type C meeting with the agency on December 16, 2013.

In particular in its letter of May 16, 2014 to the company, the FDA gave guidance on assessment methods and endpoints that Provectus has incorporated into its Phase 3 submission.

Shareholders received a letter from the CEO dated July 8, 2014 that detailed these interactions with the FDA.

The letter read in part, the primary endpoint of the study is progression-free survival, PFS, assessed using standard RECIST 1.1 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. And we'll measure patient reported outcomes to better characterize the relationship between complete response and symptoms of locally advanced cutaneous melanoma, such as pain and bleeding.

In a few minutes, our chief technology officer, Dr. Eric Wachter, will further address the Phase 3 press release and the function of INC Research and the importance of their involvement in ensuring our Phase 3 is conducted appropriately.

However, as CFO and COO, I will address the non-technical side of the Phase 3 study.

One of the issues with any clinical study, and of course our Phase 3 trial, is a big expense and I want to reiterate that Provectus has the funds available to complete this study entirely.

As of September 30, 2014, we had approximately 18 million cash on hand, which is about what we had as of June 30, 2014, which is up from yearend 2013.

Since the end of last year, we recorded 4.4 million in cash received from warrant and stock option exercises and 7.5 million in net proceeds from the sale of restrictive common stock and private offerings offset by 9.7 million of operating cash expenses.

So, to reiterate, what we have been stating consistently since June, we have enough cash on hand at this time to fund the entire Phase 3 study. And depending on

speed of enrollment, worst case, is we're able to fund current run rate operations as the readout of the interim Phase 3 data for the melanoma study.

Furthermore, we believe that by managing variable cash expenses, due to minimal fixed costs, our cash and cash equivalence are sufficient to meet our current and planned operating needs now well into 2016.

We have the ability to curtail or defer certain expenditures and we will do so as necessary.

This means we do not anticipate needing to raise additional capital to further develop PV-10 on our own to treat locally advanced cutaneous melanoma, PV-10 in combination with the new checkpoint barcade, PV-10 for treatment of cancers of the liver, and even further work on recurrent breast cancer and proof of concept work on other indications, like pancreatic cancer, bladder cancer, et cetera.

Although, we will continue to work with our external auditors, BDO, and New York Stock Exchange to ensure we are adequately capitalized at all times, which means maintaining cash on hand such as we had at this time.

We continue to report and believe that our financial position and corporate governance are such that we will continue to meet the relevant listing requirements of New York Stock Exchange, MKT.

This brings us to moderation of our core assets, PV-10 and PH-10 platforms, starting with our Memorandum of Understanding, MOU, with Sinopharm-China State Institute of Pharmaceutical Industry, and Sinopharm A-THINK Pharmaceutical Company, Limited, which we signed shortly after our last conference call.

This MOU focuses on a definitive licensing contract including payments to Provectus. And it provides that the three entities will negotiate such a deal within 90 days of signing.

The MOU remains in effect through November 13, 2014, which date may be extended by the parties, and we are working toward a partnership.

Because ongoing discussions have not yet concluded, we cannot provide any further detail at this time. However, as you know, we were present at a major melanoma conference in Beijing last month and are working with oncology key opinion leaders globally who are very interested in PV-10 use in China.

We continue to have very encouraging discussions with Sinopharm on multiple levels and are competent that our relationship will be further formalized and a definitive partnership agreement as we've outlined in MOU.

In addition, this is not the only partnership we are considering in Asia or even in China for that matter. We have had contacts with potential partners in India, and we have two teams working in China, which are addressing treating liver cancer with PV-10 as well as using PV-10 to treat melanoma and other solid tumors.

As you can appreciate, I cannot provide much detail on any of these ongoing discussions, but our business development has progressed forward since our last call. And when licensing agreements are signed, we will disclose them promptly.

At this point, I would like to acknowledge Dr. Sanjiv Agarwala of the St. Louis Cancer Center who has presented very encouraging data on PV-10 in the last two months in Madrid, Spain; Beijing, China; Suzdal, Russia; and planning for next week in Zurich, Switzerland.

These presentations add value to us as they aid in our meeting with potential partners as well as investigators or physicians interested in using PV-10 in the Phase 3 and other clinical studies that are being designed to advance PV-10 to treat other cancers.

In addition, he was one of the co-authors of a peer review article, entitled Phase 2 Study Intralesional PV-10 in Refractory Metastatic Melanoma which was just published in the Annals of Surgical Oncology published monthly by Springer.

Aside from our interest of license use of PV-10 in China, India, and now Russia, we are confident of the systemic immunological relevance of PV-10. In other words, PV-10 primary local oblation mechanism enables local priming of the immune system and then systemic priming of the immune system.

This immunomodule touring [sp] mechanism of the systemic immunology action of PV-10 is quite profound. We expect further discussion of this from Moffitt Cancer Center this weekend at the SITC 2014 conference.

Because PV-10 can be used in combination with immune checkpoint blockade, we believe it is entirely appropriate for Provectus to consider a co-development deal with an appropriate partner.

Deal structures we find particularly relevant include Roche NewLink, Bristol Celvix [sp], or AstraZeneca insight, although there could be no assurance that such partnerships or exhibition will occur.

At an optimal inflexion point, we hope that Provectus will be acquired along the lines of sales unit access.

As I said earlier, Dr. Eric Wachter, our CTO, has some technical matters to address. And so, I will turn the call over to him now.

Eric?

Dr. Eric Wachter: Thank you, Pete, and thanks to everyone for joining us today.

Uh, obviously, the biggest news today is that we have submitted our Phase 3 Protocol, uh, to the FDA. And I'd like to go over that with you now.

We've had multiple interactions with the FDA since our Type C meeting, uh, with the Division of Oncology Products to--on December 16, 2013.

These contacts have helped us craft and refine our submission. In particular, these exchanges provided a rationale for the PV-10 Phase 3 randomized control trial in patients with locally advanced cutaneous melanoma.

This phase 3 randomized control trial with PV-10 in patients with locally advanced cutaneous melanoma will assess response to PV-10 versus that of systemic chemotherapy in patients who have diseased limited cutaneous and subcutaneous sites and who have failed or are ineligible for systemic chemotherapy.

Progress-free survival and complete response rate will be assessed using standard criteria, that is RECIST 1.1

Duration of complete response, overall survival, and effects on melanoma symptoms, such as pain, bleeding, inflammation, and infection will also be assessed.

We will also collect comprehensive data on pain medication use to allow pain data to be placed in proper context.

We're working with our CROs and clinical sites to begin patient recruitment this year as we've stated previously on earlier conference calls and in corporate communications throughout the year.

And we won't go into much detail about the study design as that will be available shortly on the clinicaltrials.gov website.

I'm sure it's of interest of you. So, we'll have that when it's publicly available.

That said, I do want to state that we plan to enroll 225 patients with a two to one randomization. Now, those of you that have been following us closely will note that this is up from 219 patients in our more recent guidance. The small change is necessary to assure that appropriate statistical power could be applied to the planned interim analysis.

Enrollment plans have started at our sites in the U.S. and Australia, leveraging nearly a decade of our experience as sponsor physicians injecting PV-10 into melanoma patients.

Pete mentioned the recent research audit and I'd like to explain why it was important that it take out when we did.

As with most large organizations, the FDA needs to have all the necessary paperwork in order to move forward on an important project, such as a pivotal Phase 3 clinical trial.

INC Research has reviewed all of our regulatory documents for PV-10 and PH-10 to ensure that we have done responsive agency. This helps to assure that our Phase 3 study is not going to be delayed by missing or incomplete paperwork.

In our last call, we stated that we are looking beyond single agent therapy with PV-10 to address the needs of patients with extensive disease, particular visceral tumors that are not injectable.

Combining PV-10 with systemic immunotherapy, such as an immune checkpoint blockade agent that was mentioned.

Immune checkpoint blockade uses drugs to target certain receptors that serve to control anti-tumor immune response by T cells.

In oncology, these drugs increase the response of T cells against cancers, such as melanoma. This approach can also be called co-inhibitor blockade or immune checkpoint inhibition.

Can now be more specific about how PV-10 might be combined with such systemic immunotherapy in the context of co-inhibitor blockade.

Dr. Shari Pilon-Thomas from the Moffitt Cancer Center will present an abstract entitled Efficacy of Intralesional Injection of PV-10 in Combination with Co-Inhibitory Blockade in a Mirroring Mouse Model Melanoma at the Society for Immunotherapy of Cancer's 29th Annual Meeting in two time slots this Saturday, November 8th, from 12:30 to 2:00 p.m. and from 6:00 to 7:30 p.m.

After she makes her presentation, we'll issue a press release providing details of her study and appropriate links to review her research.

I will note that the abstract to this poster was publicly released earlier today and showed that combination of PV-10 with co-inhibitor blockade using anti-CTLA-4, anti-PD1, and anti-PD-L1 agents in mouse models of melanoma led to increased progression in both injected and uninjected tumors.

The authors conclude that these results "support the introduction of increased--I'm sorry--support the induction of increased tumor specific immunity after co-inhibitory blockade in combination with IL PV-10 therapy."

What does this mean? Well, we believe this important work on Moffitt lays the final section of foundation necessary for initiation of combination studies with any of the major classes of checkpoint blockade agents.

Whether these be approved agents, such as Sipholomad [sp], an anti-CTLA-4 drug, Prembolism [sp] ad, an anti-PD1 agent, or emerging or investigational agent such as the many anti-PD1 and anti-PD-L1 drugs that have been the topic of intensive development efforts recently.

Until we secure a strategic partnership with one or more of the developers of the emerging or investigational agents that would allow to such agents, we are preparing to move forward with existing approved agents where PV-10 can be tested in combination with standard of care. Just as was reported at ASCO this summer for a combination of Amgents intralesional agent T-VAC [sp] with lipomad in melamona patients.

This is a cost effective approach for clinical developments since the standard therapy component is commonly reimburse by third parties.

We also remain committed to developing PV-10 for other cancers as evidenced by our negotiations in China and to developing PH-10 for skin conditions.

Our primary focus since last call has been on the drafting of the Phase 3 Protocol and on negotiations with potential partners overseas. But, these other areas of interest remain squarely on the radar and we intend to pursue them with as much diligence as we have PV-10 as a treatment for melanoma.

Cancers in the liver, and in particular hepatocellular carcinoma or HCC, we are preparing a publication documenting long-term outcome in our initial patient cohort.

This work serves as the basis for a Phase 1B/2 Protocol we are developing for implementation in Asia where HCC is a major public health crisis.

Interestingly, the design of the study would be virtually identical to that of our combination work I just mentioned with immune checkpoint blockade agents for melanoma, but in this case, we'd compare PV-10 plus local standard of care for HCC versus standard of care across several countries in the Asia Pacific region.

On the topic of PH-10, we are in the process of manufacturing study drug for the next step in psoriasis, which is a clinical trial to assess changes that may occur in psoriatic plaque upon daily application of PH-10.

In this 30 patient trial, subjects will apply vehicle for four weeks as lead in to application of PH-10 for four weeks.

Biopsy specimens collected before and after these two treatment courses will be compared on a patient by patient basis for changes in structural and immunologic characteristics of the skin.

Psoriasis at least--psoriasis is at least partially the result of abnormal immunologic patterns in the affected skin and we expect the study to shed light on clinical observations from prior studies of PH-10 in both psoriasis and a topic dermatitis.

Clinical work in this area is expected to start early in the first quarter.

That covers the material we want to discuss.

So, Mike, I believe 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 speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

One moment, please, while we poll for questions.

Our first question comes from the line of Jason Kolbert with Maxim Group.

Please proceed with your question.

Mr. Robert LeBoyer: Good afternoon, everybody. This is Robert LeBoyer, part of Jason Kolbert's group at Maxim.

And congratulations on this nice progress.

One of the first questions that come to mind would be when would you expect to start this trial? And any clues or projections as to how long the patient enrollment will take or when we might see data?

Mr. Peter Culpepper: Thank you for the question.

We had said that we expect the enrollment to start this year. So, we would expect this--the enrollment to start this year.

Besides, as Eric had indicated, in the U.S. and Australia are preparing now.

We expect interim readout hopefully by the end of next year.

So, the earliest we could see interim data readout, which is, as Eric said, the statistical powering allows for interim data readout. And this, of course, depends on the enrollment, would be--and the events that are generating would be--and this is certainly is

meaningful from a data standpoint--would be the end of, uh, next year would be the earliest. So, that's our target for the Phase 3, uh, data readout. Eric?

Dr. Eric Wachter: Thank you, Pete.

Mr. Robert LeBoyer: And did you say that was an interim readout at the end of next year?

Mr. Peter Culpepper: Yeah, that is correct.

With the first meaningful data for this, uh, uh, Phase 3 study would be interim data readout. That is correct.

And that--and from my--from our discussions with potential partners and for this study, interim data readout is the most meaningful initial readout.

Mr. Robert LeBoyer: Okay. And what about the full set of data?

Mr. Peter Culpepper: Well, the full set of data would be the--uh, the end of the following year would be the best case. And again, this is very much dependent on how fast we do the enrollment, but we're projecting that to be the end of the following year, the full data readout.

Mr. Robert LeBoyer: Yeah, of course. Enrollment's can be--.

Mr. Peter Culpepper: --For further--yeah, this would be further detailed when we look at the study design that is on clinicaltrials.gov.

Dr. Eric Wachter: Right. This is Eric.

So, the study design on clinicaltrials.gov will give, uh, the design parameters that were used in the statistical design of the study. And that is predicated on the 30 month total study length, uh, which, as Pete suggested, it could be as short as 24 months, um, and best case scenario.

Worst case scenario is 30 months.

Mr. Robert LeBoyer: Okay.

Mr. Peter Culpepper: Thank you, Eric.

Mr. Robert LeBoyer: Okay, terrific. Thank you, and congratulations on the progress.

Mr. Peter Culpepper: Thank you so much.

Dr. Eric Wachter: Thanks.

Operator: Thank you.

Our next question comes from the line of David Cugeski [sp], a private investor.

Please proceed with your question.

Mr. David Cugeski: Yes.

Um, not sure if this was answered yet, but, um, how long do you expect it would take to, uh, hear whether you have the permission to proceed with phase 3?

Mr. Peter Culpepper: In the--.

Dr. Eric Wachter: --Okay, we commented on that and we said that we expect to hear something back, uh, within 30 to 45 days from the agency.

Mr. David Cugeski: Okay, gotcha.

Sounds great. Good luck. I'm long and, uh, keep them fingers crossed.

Dr. Eric Wachter: Thank you.

Mr. Peter Culpepper: Thank you.

Mr. David Cugeski: Thank you.

Operator: Thank you.

Our next question comes from the line of John Handsberg [sp], a private investor.

Please proceed with your question.

Mr. John Handsberg: Yes. Hi.

Um, thank you, guys, for having this call.

Uh, I wanted to speak a little bit about in the 10-Q, it mentions, uh, uh, uh, a current money raise.

And, uh, I just wanted to know more about that, which we--you know, especially in regards to the August call that said that we had enough--you guys had enough money to go through 2015.

So, what has changed from then until now?

Mr. Peter Culpepper: Thank you for that question.

As we said--and you are correct. Uh, we continue to point out that we have funding essentially for 18 months. So, now, we're saying we have funding well into 2016.

If you notice in our comments on the--in this call, we made reference to the fact that we want to, in our interaction with external auditors, BDO, and the New York Stock Exchange, to ensure we are capitalized adequately at all times.

So, what that means is we believe it's appropriate to maintain the cash on hand. So, the runway continues to go out, but we need to offset cash burn either with non-diluted forms of financing, which speaks to our efforts to secure a regional license transactions or through financing efforts such as we stated in the 10-Q with that--a private placement.

So, from the standpoint of the company and Eric and I, of course, as many on the call are very committed long shareholders, we know that the interest is to minimize

dilution. So, we want to at all times ensure that we have the proper capitalization in our ongoing efforts to remain listed on NYSE and KT and to meet the requirements of our actual auditors BDO.

Mr. John Handsberg: Well, just as a follow up, I mean, is it--was there a need to do it now? I mean, you just mentioned that you, you know, submitted the phase 3 and, you know, I'm guessing that, you know, deals with China or others are not far off.

What was the need to do this now with the stock at $1?

Mr. Peter Culpepper: Okay. That--I appreciate that question.

Think of it in terms of looking at the end of the quarter from the balance sheet as a snapshot in time.

So, we're looking at the cash on hand at the end of September in this case. And so, we want to have adequate cash on hand at the end of September for purposes of the BDO review of the financials. That's very important.

So, for snapshots in time, we have to think in terms of what we need to do from a capital structure irrespective of what we're discussing with potential partners like Sinopharm.

So, we have to balance the needs of a snapshot in time for the financials with what we know to be our efforts for securing and our hopes to secure, uh, non-diluted financing.

Mr. John Handsberg: Thank you.

Mr. Peter Culpepper: I hope that helps.

Mr. John Handsberg: Thank you.

Mr. Peter Culpepper: Thank you.

Operator: Thank you.

Our next question comes from the line of Bruce Benzell [sp], another private investor.

Please proceed with your question.

Mr. Bruce Benzell: All right.

Uh, before I get onto my question, Peter, I'd like to follow up on John's question.

Are you saying that you will continue to raise capital as necessary to maintain the $18 million of cash?

Mr. Peter Culpepper: Yeah, I appreciate that follow up question.

And this is where in the--in my comments, that's what I'm saying that we are continuing to work with BDO and New York Stock Exchange to maintain cash on hand.

It's not--this is not an exact science as some people have heard me say. There's no--it's a gray topic as to exactly how much cash at the end of each quarter.

But, it's very appropriate to always have the necessary runway or enough cash on hand so we continue to say that we have more than a 12 month period. I'm shooting for always an 18 month period, which speaks to the--.

Mr. Bruce Benzell: --All right--.

Mr. Peter Culpepper: --Our understanding of what we're listed under.

Mr. Bruce Benzell: In the next 12 months, if you don't receive cash from another source, you will find a way either in a non-dilutive or diluted way to raise the cash?

Mr. Peter Culpepper: Yes. I--yeah, I think that's a better way to, uh, be very specific about it. If we're not able to raise or to secure non-dilutive cash, then we will need to go to the capital market to offset burn. That's right.

Mr. Bruce Benzell: Okay.

Mr. Peter Culpepper: And that's the importance of generating meaningful data and the importance of monetizing the assets to minimize dilution.

Mr. Bruce Benzell: Okay.

I want to get to, uh, Eric a little bit and talk a little bit about the protocols.

Congratulations on getting phase 3 done.

Uh, my question, uh, obviously a lot of us felt, uh, frustrated with the delays and I'm wondering to what extent have you worked with the investigation review boards of each of the hospitals or research centers that you're working with.

Uh, can you tell us about adding any additional sites at this time?

Um, and, uh, you know--why don't you answer that first?

Dr. Eric Wachter: Okay, Bruce. Thanks.

Uh, we have, uh, been pursuing a program throughout the year to develop, uh, additional relationships with investigators, uh, geographically in the U.S. and Australia and potentially in other parts of the world, uh, as part of our expand access protocol that's currently open, um, and with the expectation that as we develop relationships with those, uh, investigator insights that we would be leverage those relationships, uh, to expedite opening a study, uh, such as the phase 3 study at those locations.

Uh, I think that's a successful strategy and I'm, uh, comfortable with the, uh, success we've had at that so far.

Uh, we have several, uh, investigator meetings in the coming weeks that we will be using to provide additional, uh, information to potential new investigators to our program. Uh, and to identify those that might be appropriate candidates for incorporation with Phase 3 study.

So, I think, uh, we have a good handle on how to build out the study at the investigator and institutional level.

Mr. Bruce Benzell: So, you're not ready to name any new meetings or new centers? And does having the protocol out there help with this process?

Dr. Eric Wachter: Uh, having the protocol out there helps tremendously. And no, I won't, uh, be naming names. I don't kiss and tell.

Mr. Bruce Benzell: Okay.

And then I--the final follow up is to what extent is your experience with the melanoma, uh, helped you to design, uh, the liver protocol?

The last I heard you were working on a liver, uh, phase 2/3 protocol for liver and you didn't mention that.

Uh, can you talk about, uh, lessons learned from melanoma and how that's going to go into further research--further trials?

Dr. Eric Wachter: Absolutely, Bruce.

As I eluded to in my prepared comments, uh, we are using, uh, common features between, uh, the expected combination study in melanoma that we talked about, the checkpoint blockade agents, uh, and, uh, we're moving the hepatocellular carcinoma, the liver cancer program, forward.

Uh, what we have learned in the, uh, relatively recent past is with our experience in Asia that it will be necessary, uh, going into China to do some additional phase 1 work and that has colored our design parameters for, uh, the next phase of, uh, HCC work to use this 1B/2 approach that, uh, I point out from my prepared comments has been successful with Amgen and a number of other, uh, uh, sponsors in recent, uh, years as a way to expedite, uh, development of a drug from, uh, the phase 1, uh, safety phase into a, uh, very robust randomized phase 2 study in a quick fashion.

Operator: Thank you.

Our next question comes from the line of Ed Gollum, a private investor. Please proceed with your question?

Mr. Ed Gollum: Uh, yes, thank you.

Um, the parties that we've been talking to in China, the interested parties there, have they, um--have they requested, uh, Provectus and received significant amounts of PV-10 to perform their own treatment, uh--you know, clinical treatment trials regarding liver cancer or other forms of cancer there?

Mr. Peter Culpepper: We're certainly not aware of any PV-10 being shipped. It's--any PV-10 going into China would have to be part of a clinical study that would be public.

Reagent grade Rose Bengal can be purchased and is used globally for experiments. So, that's--we know that's the case.

Uh, for PV-10 use, we will--we have said in the Sinopharm MOU announcement that we control the supply chain. So, we control the production and the distribution for clinical purposes of PV-10.

Eric, you had a question--.

Mr. Ed Gollum: --Correct. But, I would think that if I was one of the interested parties in China, I would, uh--since I'm not governed by the FDA on that soil, um, in order for me to sign a contract involving money, it would seem logical to request of you doses of that and perform my own testing before signing a binding agreement.

Um, is that possible? Or--?

Dr. Eric Wachter: --With China is a signatory entity and the International Conference of Harmonisation, ICH. So, China participates in clinical--global clinical studies just like other major jurisdictions.

So, for a--for Sinopharm or for any pharmaceutical entity that we're talking to in China, they're interested in participating in our clinical development in China. So, they want the protocols filed with their own FDA. And then we do the appropriate release testing. We control the supply chain, but the appropriate--we release testing of PV-10.

What they're focused on is the protocol. The protocols for liver and for melanoma, particularly, those two protocols and they're focused on the data supporting their interest and use of PV-10 for their patients.

Mr. Ed Gollum: So, it sounds like they're not doing any additional testing on their own. They're just going by, you know, the FDA guidelines and your own protocols, et cetera, correct?

Dr. Eric Wachter: Well, these are international guidelines, ICH guidelines, which are the same in China as they are in the U.S.

And so, uh, an investigational product such as PV-10 is very tightly controlled. Uh, we are not providing, uh, bad investigational product to China at this time. And so,

uh, any hypothetical work that might be done in China would have to be with, uh, some other source of Rose Bengal and PV-10.

We're the sole supplier globally as far as we know of, uh, pharmaceutical grade, uh, material.

Mr. Ed Gollum: Okay.

Dr. Eric Wachter: So, we have [unintelligible].

Mr. Ed Gollum: I think you answered my question. Thank you very much.

Dr. Eric Wachter: Thank you.

Operator: Thank you.

Our next question comes from the line of Stewart Fute [sp], a private investor.

Please proceed with your question.

Mr. Stewart Fute: Hey, Pete and Eric. How are you?

Mr. Peter Culpepper: Good. Thanks for calling, Stewart.

Mr. Stewart Fute: Thanks.

Uh, my question has to do--I know there's been a lot of talk of the, uh, trials, the, uh, phase 1B, phase 2 trials in China.

Could you talk a little bit about timing for those trials? Give us some information about that? How long they take? Are they comparable to FDA?

Dr. Eric Wachter: Uh, the process is very similar to the process in U.S.

Again, alluding to the previous caller, uh, because China, like the U.S. uh, uh, is under the constraints of the International Conference on Harmonisation, ICH.

Uh, and so, standards for clinical practice are global.

Um, we will expect to be working with a Chinese partner to facilitate launch of a clinical program in China. Uh, that's one of the prime reasons to develop a relationship with a company such as Sinopharm is to provide us with, uh, the appropriate support, uh, in China to do that type of work.

Mr. Stewart Fute: And can you piggyback on the data from your FDA phase 2 trial so that you don't have to start from scratch at least on the, uh, melanoma?

Dr. Eric Wachter: Uh, in melanoma, we're in a special case because we're entering into an international pivotal phase 3 study.

Uh, for earlier phase development, uh, there are requirements meet with China.

Mr. Peter Culpepper: Someone has some background.

Dr. Eric Wachter: Operator, I think you need to cut off all the callers so that we can get this taken care of. And I'll continue to address Stewart's question.

So, uh--so, Stewart--so, the International Conference of Harmonisation applies globally. Uh, we're working with, uh, potentially a partner in China to assure that clinical work is done, uh, uh, effectively in China.

Because of, uh, special requirements in China for early stage clinical development, uh, there may be some additional phase 1 work that would be required and that's one of the motivating factors for, uh, moving forward with the 1B/2 study design versus a 2/3 study design that we had previously anticipated.

Operator: Thank you.

Our next question comes from the line of Ted Kidd, a private investor.

Please proceed with your question.

Mr. Ted Kidd: Hi, guys.

Um, glad to see all the work that you're doing is finally starting to bear a little fruit here.

And I'll just--I have a simple question. I don't know if you'll be able to answer this or not, but--so, on a scale from, uh, one to 10, how close did this put us to being able to, uh, complete, uh, some type of, uh, monetary deal, uh, upfront payments or, uh, what have you with, uh, Sinopharm?

Mr. Peter Culpepper: Okay. Thanks for that question.

We said on the last conference call that most big pharma or partnerships with companies like Provectus and other partners, most deals go down in phase 3.

So, we can say that approximately 80 percent of transactions occur once the company starts phase 3.

So, that is very supportive of why it's so important that we have started this phase 3 officially. And that helps in the Sinopharm discussion. It helps in all of our interaction with potential partners globally. So, that's the best way to put it.

Now, within the phase 3, there's different points in time in the phase 3 that makes sense for a transaction to occur. And there's specific case examples of what we could refer to, either beginning of phase 3, middle of phase 3, end of phase 3.

But, for Sinopharm, we should keep in mind--and for, say Sinopharm and we'll include companies--partners in India. We're focused on the importance of the phase 3 melanoma study, but also for liver cancer.

So, this liver 1B/2 that Eric refers to, as soon as he finishes that trial design, we'll announce that. And then that will be very important.

And we touched on this also last conference, that will be very important to consummating the transaction in both China and India for purposes of moving forward in those, uh--in those regional areas.

I hope that helps somewhat.

Mr. Ted Kidd: It does. And you're referring to return of, uh, uh, the, uh, data for the--or first data return from the first phase 3 trial.

Now, were you referring to the fiscal year or the calendar year of 2015?

Mr. Peter Culpepper: Yes, as far as the, uh--and as far as the interim data, I was referring to the end of 2015.

So, for the interim data to be available, the projection would be by the end of 2015.

This will depend on enrollment. So, the more sites and the more patients that we can enroll, the quicker we can get to the interim data readout, hopefully. So, that's where our effort will be, enrolling as quickly as possible in the melanoma study, the phase 3.

But, that's not necessary to actually have any data from the phase 3 for China Sinopharm discussion and a discussion with other potential partners in, say, India, et cetera.

All those--in India and China, what they're interested in is having the protocol itself available. So, that--so, they just need to have the protocol that's actually completed. Like we have now with the phase 3, that protocol is completed for purposes so they can start treating patients in China and India with that protocol.

And same thing in live cancer. As soon as we have that protocol finished, we will then have it available so those partners can be working with us to get the drug approved in their, uh, respective areas.

Mr. Ted Kidd: That's great. I think you got to the nut of my question. I appreciate it.

Good luck. And let's keep pushing forward.

Mr. Peter Culpepper: Yes, sir. Thank you.

Mr. Ted Kidd: Thanks.

Operator: Thank you.

Our final question comes from the line of Jerry Meyer with Meyer Financial.

Please proceed with your question.

Mr. Jerry Meyer: Well, I think, um--well, first of all, let me say I just really appreciate, uh, all the good work that you're doing and the way you're keeping people informed.

Um, uh, let me just clarify a couple of things.

So, I appreciate the last couple of answers that you gave.

Um, on the phase, um--on the phase 3 trial, we're saying this is an international trial in an international protocol; is that correct?

Dr. Eric Wachter: Yes, that's correct.

Mr. Jerry Meyer: Okay. Which obviously varies somewhat from just a U.S., um, based trial and protocol.

So, what you're saying is that the--having the phase 3, uh, protocol, uh, filed and the comments back from the FDA is a very important to potential partners, uh, internationally. Is that what we're saying?

Mr. Peter Culpepper: Well, certainly we're saying that what the partners like Sinopharm want to do is they want to start using PV-10 in the country as quickly as they can. And we--and so for them to do that, they need to have the protocols filed with, say, in this case, the China FDA.

Eric will file that protocol with China FDA and with India FDA as quickly as he is able to. Like we said in the press release today, within the 30 to 45 day and as we're working with these potential partners.

This is going to be challenging to put a finger on exactly the timing here, but our objective is to get this phase 3 study available in important jurisdictions that would include, of course, besides the U.S. and Australia, China and India, other jurisdictions where there's a need for what we're doing in the phase 3 with PV-10 and the EU, places like Mexico, South America.

So, this would be a number of places, potentially, where we'll have efforts to--in China and India, uh, particularly, uh, in concert with a partner.

So, it's the same protocol that's filed. It's the same protocol that's used. It could be a question of how quickly we can get the site actually enrolling in a particular area, say in Beijing or Mumbai or what have you.

Mr. Jerry Meyer: So, no enrollment--no site--well, you're recruiting patients and sites now and you can do that prior to the FDA's, uh, comment or approval of the protocol; is that correct?

Mr. Peter Culpepper: Yes, that is--.

Dr. Eric Wachter: --We can recruit sites.

Mr. Peter Culpepper: Yes, we can recruit sites. And we have spoken to very well known, very well respected physicians in China, India globally. There's a widespread interest in this drug, uh, in PV-10.

So, we have very good relations right now with key individuals, key sites literally throughout the world who want to use PV-10 right now for patients.

This speaks to the fact that there is a significant need globally for this type of drug to be used right now.

And so, the first critical step has been accomplished, as protocol filed with the FDA. Now, the next step will be to have this protocol available in the individual sites throughout the world.

But, we know the event [unintelligible]. This is where we--when we mentioned people like Dr. Agarwala presenting at these different international conferences, we regularly get a very dramatic response from people wanting to use PV-10.

They want to be in the studies--uh, conduct the studies themselves. They need it for their patients.

So, there's a significant need to come--that's come to our attention, which is why we are active not just in west and obviously that's critical for value of what we're doing, but we know that we can get the data for the purpose of getting it approved in the U.S. also EX-US [sp].

So, the data that we generate China and India will come back for purposes also, uh, in the, uh, U.S.

Mr. Jerry Meyer: So, um, the phase 3, um, uh, protocol is not filed in China, for example, until, uh, the phase--until the comments are completed or the approval is given by the FDA here; is that correct?

Dr. Eric Wachter: Yes, that's correct.

Uh, the U.S. FDA is considered to be the global authority. And so, it would be imprudent to send out the protocol to multiple other regulatory authorities until we have heard back from them.

Mr. Jerry Meyer: And patients cannot be enrolled until the protocol is, uh, approved; is that correct?

Dr. Eric Wachter: Protocol isn't exactly approved. The agency can put a clinical hold on a study if they find significant, uh, shortcomings that might affect the safety of patients, for example. We don't expect that to be the case.

Uh, they can provide very firm recommendations for things that they would like to have changed or they can make general comments.

We expect to have something in one of the latter two categories received from the agency in this 30 to 45 day window.

Mr. Peter Culpepper: We could make a general comment that what we're doing right now in our global expanded access study, we're using PV-10 for capacity use purposes right now that would be very similar to how it's being used in the phase 3 study.

So, the FDA is well aware of this already, how we're using PV-10 in the active arm of the phase 3 study.

Dr. Eric Wachter: Yeah, that's correct. The active arm and the phase 3 study is no different than what we've been using in our expand access protocol for three of four years now.

Mr. Peter Culpepper: We have a lot of experience in using PV-10 in this fashion, which is a very important aspect here. We're very knowledgeable of how to treat the patient's disease. We're very knowledgeable in the adverse event profile. All the aspects of treating patients with PV-10, we've gained a lot of experience.

Dr. Eric Wachter: Yes, that's correct. And Pete, part of the work that INC Research did in their audit of our regulatory files was to confirm that we have been reporting on an annual basis the [unintelligible] information that we're required to report. Uh, the numbers of patients treated under different protocols, adverse events that occur under various protocols, and so on.

And the--as we mentioned in the prepared comments, they found no shortcomings in that, uh, document chain.

So, uh, that shows that we have been, uh, providing the agency with the information they need to be able to put the PV-10, uh, aspect of the phase 3 study into proper context on the flipside for the compared armories and standard, uh, chemotherapy regiments. So, there's really no question about those.

Mr. Jerry Meyer: Is there a difference, uh, in acknowledged, uh, standard, uh, chemotherapy treatment?

Uh, I had somebody that made a comment at one point that, uh, the standard of chemotherapy that you selected to use and, you know, it's comparative to Rose Bengal.

Somebody said that's not really the standard. I don't know. Are there different standard chemotherapy regiments that you can select from? And is there a reason why you picked the one that you did?

I mean, I don't know much about this. I'm just commenting from some comments that were given to me.

Dr. Eric Wachter: Sure.

Uh, so, we chose that based on the recommendations of the National Conference of Cancer Network, which is an organization that defines the standard of care for oncology in the U.S. by disease indication.

So, we looked in the melanoma guidelines for physicians treating patients with, uh--according to standard of care.

And, uh, patients that we are going to be studying, uh, chemotherapy is one of the standards of care. And the specific regiments that we've chosen are among, uh, a range of options that are available to use for that, uh, particular chemotherapy standard.

Uh, those--as I mentioned, range of options imply that, uh, if you talk to an individual, uh, investigator, physician, or expert in the field, uh, there is some disagreement over what might be the best or the worst or the middle of the ground, uh, choice for regiments.

We chose, uh, the one that we--ones that we chose because they are very clearly demonstrated in literature. So, we knew how to, uh, project what would happen to patients on those, uh, regiments and they are very commonly used as comparators in oncology trials in melanoma.

Mr. Jerry Meyer: Well, thank you very much. And last--one remaining question on the memorandum with, uh--with China.

Is there anything that you can share that would give any insight as to things that you have learned, in particular, that are maybe more important than others in terms of, uh, either establishing these memorandums of understanding or how they're negotiated?

Mr. Peter Culpepper: We can certainly say in our discussions with potential partners globally, there is a tremendous interest in what we're doing in treating cancer.

The fact that we're treating cancer locally with such an effective--based on all the data that's presented has a very significant efficacy, the complete responses. That's met with tremendous interest. The interest in the data has been tremendous. The fact that we had this recent publication that we referred to, Annals of Surgical Oncology, that's been very helpful.

Data showing that the drug does what has been presented at the conferences has been helpful in these discussions.

So, we're actually doing what the companies that we're meeting with want us to do. We're presenting--we're producing data, we're presenting and now starting definitive work in a phase 3 protocol that meets what they expect should be done for these patients.

So, we've had actually very good interaction, uh, in this part of us developing as a company, working with these--and this why we have so many advisors on our strategic advisory board. We have excellent relationships. It's just a question now of when a partnership is entered into, we believe.

Mr. Jerry Meyer: Would you expect that there could be any kind of restrictions or changes that would come about in what you had envisioned that might alter the, uh--

whether or not, you know, those partnerships are, uh, uh--they--you know, what you really wanted to accomplish, uh, from a financial perspective?

I mean, um, obviously--I mean, any restrictions on either how or where you could use funds or anything else that would--I mean, anything that have come forward that could be--you know, I don't know what you could talk about.

But, um, yeah. I guess that's all I can say.

Mr. Peter Culpepper: There are different--there are certainly different transactions we review--we refer to as precedent transactions. And we refer to those in our 10-Q filed today as well as the prepared comments.

There are different types of transactions and there are different discussion points that we are currently having.

So, we're trying to evaluate what's best for shareholder return on investment. We're very cognizant of that. And we're trying to balance the need for generating data as quickly as possible and meaningful fashion so that we can get to this overall approval of, uh, PV-10 and PH-10 for treating patients globally in very--in a very profoundly positive way.

Mr. Jerry Meyer: Thank you very much. I appreciate your good work.

Mr. Peter Culpepper: Thank you.

Operator: Thank you.

We do have one final question from the line of Bill Hannig [sp] with Network 1 Financial.

Please proceed with your question.

Mr. Bill Hannig: Hello, guys. Can you hear me?

Mr. Peter Culpepper: Yes, we can.

Mr. Bill Hannig: Hello? Okay. I think I had the mute on. Sorry.

I just wanted to congratulate you guys on getting into the phase 3. It's wonderful news.

Um, and I wanted to clarify. Am I right to say that you can start injecting in the phase 3 patients right away now in the locations that are currently doing the compassionate care?

Dr. Eric Wachter: No. No, that's not correct.

We have to, uh, complete, uh, IRB approval for any protocol. So, we have to go through that process, contracts, and so on.

So, now that we have protocol, we are able to initiate all of that work.

Uh--.

Mr. Bill Hannig: --So, that's--.

Dr. Eric Wachter: --As we mentioned earlier--what I mentioned earlier, uh--.

Mr. Bill Hannig: --That's with the hospitals themselves, uh, Eric? That would be with St. Luke's and so forth?

Dr. Eric Wachter: Yes, absolutely. So, I mentioned earlier about, uh, getting additional investigators in sites involved. That's all part of the process of developing the relationships that allow us then to execute that, uh--that last, uh, bit of the work in a timely fashion.

Mr. Bill Hannig: And when would you estimate that that would--how long would that take, typically?

Dr. Eric Wachter: So, again, we're projecting that we will be able to enroll our first patient before the end of the year. Uh, we'll work very diligently, uh, submitting the protocol to the agency and that opens up a whole new, uh, category of work.

Um, and so, we've changed, uh, responsibilities, uh, very quickly and we're working on that aspect of execution now.

Mr. Bill Hannig: Okay, great.

And then the other question I had will expanded protocol remain open?

Dr. Eric Wachter: Uh, yes, I anticipate that that will be the case. Um, and, uh, it would not cannibalize patients from the phase 3 study because it has a very important exclusion criteria and that if you're eligible for another study with PV-10, you cannot, uh, enroll in extend access protocol.

Mr. Bill Hannig: Okay, great.

And then the last question I had was, uh, Australian approval. Is there any update on that front?

Dr. Eric Wachter: Uh, no, we don't have any additional guidance on that for you.

Mr. Bill Hannig: Okay.

Thank you very much.

Mr. Peter Culpepper: Thank you, Bill.

Operator: This concludes our question and answer session. I'd like to turn the floor back over to management for closing comments.

Mr. Peter Culpepper: Thank you, everyone. We'll look forward to do this at the filing of 10-K unless we have a significant corporate event in which case certainly we will do a conference call earlier than the filing of the 10-K.

Thank you very much. We appreciate all that's--all the interest and we're going to be dedicated to moving this forward as quickly as possible for shareholders and patients in the coming literally days, every day, the days, weeks, and months.

Thank you very much.

Operator: This concludes today's teleconference.

You may disconnect your lines at this time.

Thank you for your participation.