Provectus Biopharmaceuticals, Inc.
2015 Third Quarter Business Update
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Operator: Greetings, and welcome to the Provectus Biopharmaceuticals Third Quarter 2015 Business Update Conference Call.

At this time all of the 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.

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

Please go ahead, sir.

Mr. Michael Porter: Thank you, Kevin.

Good afternoon, everyone, and welcome to the Provectus Biopharmaceuticals Third Quarter Business Update Call.

At this time, I want to remind all listeners that this call contains 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 and such forward-looking statements may be identified by the use of terms such as anticipated, believe, could, estimate, expect, intend, seek, may, plan, predict, project, will, and other similar terms.

Forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to material differ from those described in the forward-looking statements. You should not place undue reliance on forward-looking statements. Such statements are made as of the date such statements are made. We undertake no obligation to update such statements after this date.

Risks and uncertainties that cause our actual results to material differ from the forward-looking statements, including those discussed in our filings with the Securities and Exchange

Commission, including those described in Item 1A of our Annual Report on Form 10-K for the year ending December 31st 2014.

Having completed our preliminary matters, I want to introduce Peter Culpepper, COO and CFO of Provectus.

Good afternoon, Peter. The floor is yours.

Mr. Peter Culpepper: Welcome, everyone, and thank you, Mike, for that introduction.

This call is the most recent in a series of investor calls to which we have committed Provectus's management and coincides with the filing of our annual and quarterly reports with the SEC. Our objective is to increase the transparency of our operations and to provide additional opportunities for interaction between stockholders and management.

For especially notable breaking news, such as a potential partner transaction, we will hold additional calls to address any such development.

We are coming to you live from Las Vegas for this call. However, we don't throw the [unintelligible] to Provectus. We conduct all aspects of our operations with prudent consideration and planning.

In our previous call from Atlanta, and in a letter to stockholders published on our website on October 15, we presented the five clinical and business value proposition pillars of PV-10 and PH-10, as well as our three key focus areas. You can review these at your leisure on pvct.com. But, for now, I want to reiterate them because they provide the strategic context needed to understand our operations in the most recent quarter and in future quarters.

The first pillar is our intellectual property. We hold a number of patents covering both PV-10 and PH-10 in the U.S. and globally. Such patents form the basis for monetary success for any biopharma firm, and we believe they will allow us to maximize the financial rewards that we seek to achieve as we work to successfully further develop our investigational drugs.

The second pillar is our control of the drug substance and drug product supply chain, which offers further protection to our intellectual property portfolio underpinning and complementing the value of our patents.

The third pillar is the regulatory guidance we receive from the FDA and the U.S. and its counterparts in other nations. We believe that we have worked very hard to ensure that we achieve clear communication with our regulatory authorities. We have [unintelligible] to treat patients in the various countries where PV-10 has been used and any additional countries we expect to also use PV-10.

Fourth is the mechanism of action for both PV-10 and PH-10, which we continue to research so as to be able to optimize their use and guide advanced development in treating oncology and dermatology indications.

The fifth, and final pillar, are the clinical study designs that generate clinical data to support potential approval of PV-10 and PH-10 for their respective indications. There are multiple studies here, not just the Phase 3 of PV-10 to treat locally advanced cutaneous melanoma. We also include other studies, both public and recruiting [sp], not public and those in process of becoming public.

Our three focus areas in business and corporate development are (1) more and enhanced company and PV-10 visibility and awareness, (2) nurturing co-development of PV-10 drug combinations with big pharma, (3) other strategic activity, such as regional licenses, collaborations, investments, etc.

Let's start a discussion of these pillars and focus areas with an update on our clinical trials. These include our Phase 3 trial for PV-10 as a treatment for Stage 3 melanoma, our Phase 1b-2 trial of PV-10 in combination with pembrolizumab, an anti-PD-1 drug approved by the FDA and marketed by Merck as Keytruda, as a treatment for Stage 4 melanoma, our ongoing study on PV-10's use in treating cancers of the liver and our upcoming Phase 1b-2 trial in treating primary liver cancer and our work with other solid tumor indications. After that, I will update you on developments related to PH-10, our dermatological treatment for psoriasis and atopic dermatitis, along with inflammatory dermatoids [sp] in general.

Our Phase 3 clinical trial of intralesional PV-10 as a melanoma treatment is progressing as we expected. We are actively recruiting at St. Luke's University Hospital and Health Network [sp] in Easton Pencil--Easton Pennsylvania at the University of Louisville Medical School in Kentucky and at the Atlantic Health System located in Moorestown, New Jersey. Other sites are now also listed on clinicaltrials.gov and more will be added. We expect to have other sites for the U.S., Australia and elsewhere joining the study soon.

As noted in our previous call, we are seeking 225 patients for this study. The primary outcome measure is progression-free survival, PFS, to be assessed every 12 weeks up to 18 months. The secondary outcome measures include complete response rate, CRR, and its duration to be set

every 12 weeks up to 18 months and overall survival to be assessed every 12 weeks up to 18 months. Unlike our Phase 2 study, which was a single arm study, the Phase 3 is a randomized trial. And we hope to further demonstrate conclusively that PV-10 is both safe and effective and is statistically superior to the control systemic chemotherapy. Eric will address recent developments in treating Stage 3 melanoma later in this call.

Our estimated primary completion date is September 2017, and an estimated study completion date of October 2017. When 50 percent of the events required for the primary endpoint have occurred, the Independent Data Monitoring Committee will report an interim assessment of efficacy and safety. So, meaningful clinical data could come as early as the middle of next year, which is halfway through the study, as documented on clinicaltrials.gov. I stretch the word could, and we will continue to make every effort possible to keep our stockholders and the market updated.

As I mentioned before, we are also engaged in studying the use of PV-10 as part of a combination therapy for melanoma for Stage 4 patients. Scientifically, combination therapy in cancer treatment is a rapidly maturing area, where a rational [sp] combination of agents is replacing the empirical approaches of the past. In this specific instance, we have completed development of the protocol for Phase 1b-2 testing of PV-10 in combination with Merck's Keytruda in patients with Stage 4 melanoma. And we have begun recruitment of patients.

Keytruda is an immune checkpoint inhibitor approved for patient--treatment of patients with advanced or unresectable melanoma. The PV-10 mechanism of action study's preliminary clinical findings reported last year and further updated tomorrow by Moffitt Cancer Center, which we just announced, showed that the immunologic effect of tumor ablation with PV-10 may be complementary to immune checkpoint inhibition. Companion preclinical testing of PV-10 in murine models of melanoma also reported last year shows that the therapeutic effects of PV-10 in immune checkpoint inhibition are increased when the two are used in combination. Put simply, they may work better together, especially for late stage patients. And this Phase 1b-2 study will help us prepare for potential marketing of PV-10 as part of a combination therapy with Keytruda.

When we announced the joint patent co-owned with Pfizer in August, it specifically covered the use of PV-10 to treat melanoma and liver cancers in combination with systemic inhibitors of immune system down regulation, such as anti-CTLA-4, PD-1 and PD-L1 antibodies, along with enhancers of immune system up regulation, such as IL-2 and interferon-gamma. In other words, the Keytruda work we have begun is patent protected.

Of course, melanoma is not the only indication for which we believe PV-10 has promise as anti-cancer treatment. In the third quarter data were presented at two conferences that show our

progress to date on the treatment of hepatocellular [sp] carcinoma and cancers metastatic to the liver. Eric made a poster presentation at the ESMO 17th World Congress on Gastrointestinal Cancer. ESMO GI [sp], in Barcelona at the beginning of July, he detailed data from our relevant Phase 1 study of PV-10. The main conclusion was that preliminary evidence of efficacy in treatment of cancers of the liver with PV-10 was observed. That same week, Dr. Sanjiv Agarwala presented the data at the 6th Asia-Pacific Primary Liver Cancer Expert Meeting, APPLE 2015, in Osaka, Japan. Both of these posters can be found on our website pvct.com.

What these data show is that PV-10 affects cancers of the liver in much the same way it does melanoma. More work has to be done, but we believe that these resort--results support rapidly development of PV-10 in a randomized Phase 2 study after dosing with standard of care is optimized. This is the Phase 1b-2 study we also refer to as part of Pillar number five.

What we have learned from our melanoma studies should help in developing protocols for treating other cancers. And we think the path to market for other indications will be able to take advantage of what we have--what we've learned developing PV-10 for treating melanoma.

As I mentioned in our last call, the Society of Surgical Oncology, SSO, has published an abstract describing preliminary research into use of PV-10 in murine models of colon cancer. While there hasn't been further data on treating colorectal cancers of PV-10 reported since that call,

the fact that those physicians who treat patients for those cancers are becoming aware of PV-10's potential should prove useful if and when we embark on clinical trials specific to that indication. We believe this because of the conclusion of the published SSO paper, which read, "Intralesional PV-10 treatment leads to the induction of tumor specific immunity." These results are also consistent with clinical observations reported in July at ESMO GI and APPLE 2015 regarding treatment of three patients with colorectal liver metastases in our Phase 1 liver setting.

Now, let's look at the progress we've made in our clinical studies of PH-10. We have completed patient accrual for our Phase 2 study of the cellular and immunological changes in the skin of patients receiving PH-10, our investigational topical treatment for atopic dermatitis and psoriasis. For the details of the study, I refer you to the press release issued on September 21st. For our purposes here, the important point is that patients will remain on the study for a total of 92 days. So, December 2015 will be the actual date of completion for this 30 patient trials as originally projected. After that, the data will determine our path forward with regard to further studies. That is the overview, and Eric will provide more details in his remarks on this call.

Moving into corporate developments, we strengthen our position in the Chinese market with our letter of intent with Boehringer Ingelheim (China) Investment Company Limited. We

discussed this in detail in our previous call, and I just want to reiterate that we are benefiting from their 20 plus years of experience in China, and we are building relate--building a relationship with them that may help us in commercializing and marketing PV-10 in mainland China, Hong Kong and Taiwan, as we work with the appropriate regulatory bodies. We are committed to being successful in China, in particular, and Asia in general.

Discussions have continued on the basis of a memorandum of understanding signed last year with Sinopharm-China State Institute of Pharmaceutical Industry, CSIPI, the leader among all pharmaceutical research institutes in China and Sinopharm A-Think Pharmaceutical Company Limited, Sinopharm A-Think, the only injectable anti-tumor drug research and development manufacturer and distribution integrated platform within Sinopharm Group. While our working arrangement is more developed with Boehringer, management of Provectus and senior personnel and Sinopharm, CSIPI, and Sinopharm A-Think has held numerous conference calls, have met face-to-face in both China and the U.S., and Chinese scientists on staff at Sinopharm have discussed in person PV-10 and its clinical results with various lead investigators we work with globally. Some more formal relationship with them remains an option for us in China, and will endeavor to include Boehringer as well in any future developments and potential contentions.

Efforts have been more active in Brazil as we work with potential partners there, and Latin America in general, as well as in India, as we continue our focus to enter into geographic license and our collaborations that allow us to generate meaningful clinical data more rapidly than otherwise.

Our financial position continues to be very strong. We have an effective relationship with the New York Stock Exchange and our external auditors, BDO. It is our understanding that as long as our stockholder equity remains above six million dollars, our common stock and tradable warrant listings on the New York Stock Exchange, NMKT [sp], continue as has been since we were listed May 16th, 2014.

To build public awareness for Provectus and PV-10, we have been conducting meetings with national, regional and local media journalists, including Reuters, CVS and Moore [sp]. The introductory meeting served to provide the media with necessary background on Provectus, detail of PV-10, as well as build relationships to support future company announcements. Our media relations program will continue to be a focus for Provectus.

At last, I'd like to now turn the call over to Eric Wachter, our Chief Technology Officer and Value Driver of our Clinical Development Program.

Eric?

Dr. Eric Wachter: Thanks for that thorough overview, Pete.

In my introductory comments, I'd like to reiterate some of the information Pete presented and add some additional detail on key topics. These will include status of our studies of PV-10 in locally advanced cutaneous melanoma and in more advanced melanoma patients, what we're doing to advance our liver cancer indication and status of development for PH-10. Since our last call, we've made considerable progress in all of these areas.

PV-10 represents both a unique opportunity and an incredible responsibility because the type of agent this company's working on has the potential to change the way cancer's treated around the world. PV-10 is a small molecule designed to be injected directly into tumors, thereby focusing its effect on disease tissue, while limiting exposure in healthy tissue. We believe that this focused effective tumors has the potential to educate the immune system to find other cancer cells with the same characteristics, thereby potentially having an effect on metastases elsewhere in the body.

The work previously reported by our collaborators at Moffitt Cancer Center in Tampa and at the University of Illinois in Chicago clearly indicate that this is taking place in laboratory models of

multiple tumor types. Additional information on how this translates to patients will be reported tomorrow by the Moffitt team at the Society of Immunotherapy of Cancer Annual Meeting in Washington.

With an agent that is so promising in laboratory, it's incumbent on us, the management of Provectus, to ensure that clinical trials are designed and executed to understand what this means in patients with melanoma and other cancers.

As Chief Technology Officer, it's my responsibility to carefully design the right studies to safely collect not just data, but the most appropriate data needed to understand any drug effect and detect any signal, hopefully, improvement in cancer patients. Each of our clinical studies: present, past and future, is designed with that purpose in mind.

As an example, in our current Phase 3 study endpoints are designed to answer the question is an intralesional agent alone, PV-10, sufficient to treat both symptoms and progression of locally advanced cutaneous melanoma? This powerful and challenging study design was arrived at after a lengthy consultation with melanoma experts and regulatory authorities, analysis of prior successful designs in oncology and analysis of the shortcomings of other study designs.

We previously described this study design at length. Pete has given you an overview just a few minutes ago, and a full outline is available on the clinicaltrials.gov website. So, I won't rehash that topic.

However, having completed this crucial design process, we announced earlier this year that we transitioned to execution. Starting with our initial site in the U.S., we've recently added additional sites in the U.S. and Australia, as shown on the study listing on the clinicaltrials.gov website. Those listed as not yet recruiting are in the final steps prior to opening for enrollment. We don't add sites to this listing until opening is assured, and we don't open sites without listing them on the website.

We have much work ahead as we continue to build out the study, and we will continue to add sites to the website as they're brought online, thereby, providing full transparency to patients and other stakeholders alike. Although, the first months of site initiation have gone slower than hoped, we're continuing to work on accelerating site start-up, and this is expected to continue in the present quarter and beyond.

As we noted previously, our initial focus has been on opening key strategically significant sites headed by influential investigators to establish a critical mass for the program, and we're beginning to expand from that base. In the U.S. this is a site-by-site process, where each site

has a legal and Institutional Review Board, or IRB requirements. In Australia, we've used a new national ethics application process, or NEAP, along with standard contracting indemnification template agreements for the first time nationwide. These features are representative of the constantly evolving process for the conduct of clinical trials. We can't change the ala-cart nature of site start-up in the U.S., but the nationwide approach in Australia is expect to expedite start-up once the initial site is Brisbane is active.

We're also actively engaged in bringing additional sites both in these countries and in a number of other strategically selected countries into the program. Regions of particular interest include China, Brazil, Mexico and Western Europe, and our development team is actively working to address the unique regulatory and operational needs in each country.

As the--as in the U.S. and Australia, we have meet with strategically important investigators in this region--in these regions, who will form a central core around which additional investigators and sites are added. We've also started the process for obtaining regulatory clearance to conduct the study in these regions, employing the service as a global SEROs [sp] with expertise in these regions.

Since the regulatory process is shortest in Mexico and Western Europe, we've also begun work with the help of our SEROs to prepare for clinical operations, that is the actual conduct of the

study there, and anticipate starting similar activities in Brazil later this quarter and in China in 2016.

Focus on strategically significant investigators and their sites in the early stage of the study helps assure that the study's built on a firm clinical foundation necessary for successful execution. These global leaders provide the lead geographically for other investigators in their respective regions, provide key study coordination and oversight necessary to make sure the study's conducted to the highest standards and provide crucial advice for finely tuning the study necessary to facilitate global execution. As an example, we're about to modify the study protocol slightly to address specific needs in Brazil, voiced earlier this year by key investigators.

As I noted in the last conference call, I don't anticipate that the company will provide site-by-site or patient-by-patient announcements of study milestones since this would be highly unusual for our industry. So, we do anticipate providing periodic summaries of study status. Understandably, at this point we won't be providing a summary on what has been to date a three center study. However, as we continue to add study centers, we'll monitor progress on enrollment, particularly as it relates to further optimizing implementation of the study.

We continue to expect overall enrollment to be approximately one-third from the U.S., one-third from Australia, and one-third from the rest of the world. If this balance ends up shifted

more to non-U.S. and non-Australian patients our efforts to access key investigators and the patients from different parts of the world should help assure that we have a diverse patient population that is similar to patients in the U.S.

We are, of course, also assessing opportunities that have recently come about as a result of the changing treatment options available to melanoma patients in many regions of the world, especially in the U.S. and Australia, and steps we can take to use these changes to our advantage.

Our April conference call occurred immediately after a key FDA Review Committee voted 23 to one to recommend approval of another intralesional agent for melanoma, that is T-VEC. As I noted in our last call, FDA was expected to make a decision on approval of T-VEC in the last week of October. And in fact T-VEC was approved last week and will go on sale by a commercial name Imlygic.

Similar approval in Australia is predicted within the near future. The manufacturer stated at the time of U.S. approval that Imlygic would be available soon after approval, and we expect to see this happen within the month in the U.S. We also expect the organization that delineates standard of care for cancer in the U.S., the National Comprehensive Cancer Network, or NCCN, to soon add Imlygic to the recommended treatment options for certain melanoma patients.

The label indication for Imlygic is “local treatment of unresectable cutaneous, subcutaneous and notable lesions in patients with melanoma recurrent after initial surgery.” The agency also noted in the label that “Imlygic has not been shown to improve overall survival or have an effect on visceral metastases.”

These points are very significant since the approved indication encompasses the patient population we have delineated for our Phase 3 study of PV-10 in melanoma while the additional limitation of use statement sets regulatory precedent for approval of a drug having effect limited to skin or lymph nodes. Thus, as I noted in our August conference call, when Imlygic becomes readily available as standard of care, we expect to allow its use as a comparator in those areas where it is available. Any such modifications to our study protocol should not negatively impact study timelines nor integrity study results. Quite to the contrary, approval of Imlygic not only validates our approach for seeking approval of PV-10 in patients with locally advanced cutaneous melanoma but also allows us to offer a comparator that is more attractive to patients and investigators alike. We expect to submit the necessary protocol amendment to support use of Imlygic to FDA before year’s end.

Turning to the other primary component of our development plan for melanoma, we announced in September commencement of the first clinical study of PV-10 in combination

with immune checkpoint inhibition in patients with advanced metastatic melanoma. This study was designed based on extensive input from leading investigators, who will conduct this work.

As I've indicated previously, to assess potential benefit of PV-10 for patients with advanced melanoma, this Phase 1-2--Phase 1b-2 study incorporates a modest sized single arm Phase 1b component of 24 patients with expedited safety and efficacy endpoints.

Completion of this initial phase is expected to support expansion to a larger randomized Phase 2 component, having an estimated 120 patients. The actual size of the Phase 2 component will be determined by modeling of response data observed among the Phase 1b participants, that is, the so-called effect size.

Endpoints for Phase 1b will comprise assessment of acute safety of the combination regimen, objective response rate assessed at four months, and progression-free survival. For the Phase 2 portion, endpoints will be progression-free survival, objective response rate at four months, and overall survival.

As Pete noted, we've selected the anti PD-1 drug pembrolizumab, also known as Keytruda, as the checkpoint inhibitor for this study. This class of drug has been shown to work favorably with PV-10 in mouse models of melanoma, as presented by our colleagues at Moffitt last

November at the Annual Meeting of the Society for Immunotherapy of Cancer. And as anticipated in our joint patent with Pfizer, the two drugs have largely unrelated or orthogonal side effect profiles.

These factors provide justification for conducting the study. Also, since pembrolizumab is standard of care for the study's patient population, it is standard practice to conduct these kinds of studies in an add-on mode where all patients receive standard of care.

We've already opened the first center in the study, and we're very optimistic that we can open several additional centers by the end of the calendar year. We expect to have three to five centers open in the US and one or more open in Australia by the end of the first quarter of 2016.

Since pembrolizumab is licensed in the US and Australia, we were able to commence the study without assistance of a partner. This was designed to facilitate--this study was designed to facilitate use with other drugs to enable similar testing in a straightforward manner. Thus, if ongoing negotiations with prospective corporate partners leads to interest in testing PV-10 with a different checkpoint inhibitor, or even another class of systemic drug, the design can readily accommodate such interest.

With regard to other activity in melanoma, we expect to provide an update on the status of our expanded access protocol by the end of the calendar year. And I'll note for now that approximately 140 patients have received PV-10 under this program.

We also continued to work with the team in Australia conducting the investigator initiated trial of PV-10 in combination with radiation to report ongoing results in a suitable venue. These protocols fill therapeutic niches not covered by our core melanoma studies, while also expanding our overall safety database for PV-10.

We are also continuing to sponsor mechanism studies at Moffitt and the University of Illinois Chicago, and anticipate further data from both groups to be released in coming months.

Moving on to our liver cancer indication, as Pete noted, we presented data from our Phase 1 study at two international liver cancer conferences in July, one in Europe and one in Japan. These meetings provide--provided a means to present initial data to investigators in these two important regions.

They also provided the perfect venue for announcement of our relationship with Boehringer, particularly since that has a core common goal of advancing development of PV-10 for

hepatocellular carcinoma, a major concern in many parts of Asia as well as certain parts of Europe.

Following up on a successful summer, we recently conducted an advisory board meeting in China that has helped to clarify plans for advancing work on HCC in Asia, along with possible companion studies in the West. While our current study has played and continues to play a crucial role in identifying promising indications for PV-10 in tumors of the liver, we will build on this study over the next several months to begin one or more Phase 1b-2 studies directed to addressing HCC in Asia.

Work we've been conducting to support global regulatory filing for our melanoma program aids in this process. And our fundamental design for a Phase 1b-2 study for PV-10 plus standard of care for HCC remains unchanged.

Finally, moving to PH-10, we began enrollment in our Phase 2 mechanism of action study in PH-10 beginning--at the beginning of the year. And enrollment was, as Pete noted, completed in August at our three study centers in the US.

This mechanism study is designed to probe possible changes in the immunologic, structural, and hyperproliferative state of the skin in target plaques and look for evidence of cellular atypia

following PH-10 application. The last patient will complete the final follow up in December, and we expect to have initial mechanism data early in the new year.

Data from this study should aid in further development of PH-10, with our objective to co-develop or license PH-10 with a dermatologic partner. Perhaps more importantly, we expect it to provide the basis for substantive discussion with FDA regarding the path forward from Phase 2 to Phase 3.

In addition to these readily visible activities, we've been exceptionally busy throughout the year actively supporting our two INDs for PV-10 and PH-10 respectively, updating our quality systems to be in line with pharmaceutical companies at this stage of development, and maintaining and expanding the Provectus patent estate.

To this end, we've scheduled two meetings with FDA to cover manufacturing and nonclinical portions of a possible new drug application, or NDA, for PV-10 and any supportive safety or pharmacology studies that may be needed so that, if the Phase 3 study is positive, these details won't delay review of the NDA.

One of these meetings has been completed, with the second scheduled for early next year. We expect both to provide crucial guidance for completion of the data package supportive of an NDA.

The current year, and especially the quarter just completed, has been characterized by accelerating momentum as we have achieved clarity in the path forward. However, we realize that following progress in clinical development can be frustrating, particularly when the process is necessarily opaque to protect the integrity of a Phase 3 study, or when sensitive business discussions predicated on such developments must remain confidential.

Progress in all of the areas that I've discussed; PV-10 for locally advanced cutaneous melanoma, combination work in advanced metastatic melanoma, ablation of liver tumors, and elucidation of the mechanism of action of PH-10, which is paralleling similar work with PV-10; all establish critical scientific, medical, and regulatory foundations necessary for close relationships with potential corporate partners.

In his remarks, Pete outlined various efforts we are making on this front and some of the fruits these efforts have already produced. In the coming months, we expect much further progress on this front, keeping foremost in mind the needs of both patients and our many corporate stakeholders.

With that, I believe we're ready for questions.

Operator: Thank you. At this time, we'll be conducting a question and answer session.

If you'd 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. Once again, if you'd like to ask a question today, please press star-one on your telephone keypad. If you're on a speakerphone, 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 today is coming from Joe Leo [sp], a private investor. Please proceed with your question.

Mr. Joe Leo: Yeah, this question is for Peter. Hi, Peter.

I had a brief look at the cash position that's shown in today's 10-Q. Barring a transaction with some front money, it appears that the cash burn will continue and we're going to need another raise somewhere, I would say, mid 2016. Could you comment, please? Thanks.

Mr. Peter Culpepper: Yes. Yes, indeed, Joe. So, we are very committed--as we identified in our three focus areas, we're very committed to nurturing co-development of PV-10, drug combinations with big pharma, and other strategic activity. So, both of those two focus areas would bring in non-dilutive cash.

So, we know how important it is to bring in cash to the company that's not dilutive to the stockholders. So, that is a key area of focus. What Eric detailed does support that sort of activity in the sense that the data from the 1b-2 combination study, as we articulated in the press release in September as well, supports what we believe we need to advance co-development transactions, and then also our efforts globally with strategic activity.

That being said, certainly we want everyone, which is why we have it in these remarks, to focus on our relationship with the New York Stock Exchange with the ability for us to have six million dollars in stockholder equity as the floor. So, we're significantly above that, approximately 25 million stockholder equity versus six million.

So, we have a lot of room now, but we will be very careful to look at the cash position as we continue. And we will be absolutely clear that we will ensure that we'll do what we need to, to remain with our relationship with the New York Stock Exchange and BDO so we can continue as a going--as a viable entity, as a going--without any going concern issues.

So, that all being said, we're very focused on non-dilutive financing. And that's our top priority at this time.

Mr. Joe Leo: Okay. Thanks, Peter.

Mr. Peter Culpepper: Thank you.

Operator: Thank you. Our next question is coming from Joseph Buffo [sp] from Axis [sp]. Please proceed with your question.

Mr. Joseph Buffo: Hi, Pete and Eric. How are you guys today?

Mr. Peter Culpepper: Hey, Joe. We're well.

Mr. Joseph Buffo: You know, I missed the opening remarks. I'm sorry. I was--I got on about maybe five minutes late. I don't know if this was covered. I'm going to direct this call to Eric.

Eric, what preceded the method of action work from Moffitt was their murine work, and then the scientists at Moffitt had an article. I think it was Cancer Review, whatever it was, some cancers research magazine. This was almost like three years ago where they said sometimes results are so spectacular you have to go back to the bench.

Usually it's from the bench to the clinic. We have to go back to the bench and we have to identify the method of action of how this drug is working. And in that article, they said that this is a straightforward process, that there--it should give us definitive proof one way or another, which I believe they were talking about the method of action.

Then at AACR, they released--like, 17, 18 months ago, they released the results from the first seven, basically saying that there was no--they couldn't find any tumor or any--in the bi-center through pathological--that the cancer was gone.

This report tomorrow at SITC, is this the culmination of their work where the doctor said in the magazine this should give us the answer and it should be a straightforward process that--you know, really that they should be able to prove what they were looking for?

Dr. Eric Wachter: That's a great question, Joe. So, certainly the material that will be presented tomorrow at the SITC conference--I'll use that acronym; it's much easier to say than Society for Immunotherapy of Cancer--.

Mr. Joseph Buffo: --Yes--.

Dr. Eric Wachter: --Will be a culmination of a number of years of work at Moffitt, starting with early reports at the Society for Surgical Oncology meeting several years ago.

The way this works with Moffitt, they are experts at something called translational medicine. And what translational medicine means is understanding therapeutic processes based on investigations in both model systems, typically either in-vitro, so in test tube, or in animals and in humans. And the translational part means that you frequently go back and forth between the two types of systems as you learn.

So, in this case, it was a very interesting process where some things that were elucidated in mice were then discovered to be occurring in humans. And the opposite actually happened in the clinical studies they've completed looking at human patients. And they went back to the bench and confirmed those in mice.

So, this is normal operating procedure for translational medicine groups. It allows you to benchmark what you're seeing in model systems and humans and efficiently understand what's going on in humans in a high throughput system; that is, the models.

Conferences--I like to say that conferences are--presentations are an early draft of history, just like newspapers are an early draft of history.

Mr. Joseph Buffo: Um-hmm.

Dr. Eric Wachter: A whole article would presumably be following on the heels of this presentation at SITC, but that is controlled by the researchers at Moffitt. So--.

Mr. Joseph Buffo: --But, I--my real question, Eric, as a layman myself, and I'm sure probably 95 percent of your shareholders are laymen, when I read that article--and I think it was Darnick [sp] that was being--I think it was him who was being quoted. I know that Shari Pilon-Thomas was quoted, and this was in 2012.

When they said this should give us definitive proof one way or another that this is a very straightforward study that they're doing, you know, he never spelled out this should prove--you

know, I mean, I could get the article out. But, basically as a layman reading it, was he saying this should prove the method of action? And if he was saying that, do you think anything that's happened in their testing has made it not as straightforward?

Is there anything that Moffitt has done in this particular method of action where he said, "Hey, it's going to give us proof one way or another, it shouldn't really be argued with because we're going to prove it scientifically," is--has anything changed now that they've gone into the human model? And did I read him correctly? Did I understand him correctly when he said this should give us an answer one way or another? Was he actually saying this should really spell out the method of action?

Dr. Eric Wachter: Okay, another great follow on question. I think we'll have to limit you to two.

The immune system is very complicated. And in my humble opinion, we are just beginning to really understand the complexity of it and how that can be applied in oncology.

That being said, in just the category of drugs that function based on controlling immune checkpoint processes with T-cells, there are three classes of drugs that are either commercial or soon to be commercial; the anti CTLA-4 drugs, which was the first generation epitomized by ipilimumab; the anti PD-1 drugs, which are epitomized by pembrolizumab and nivolumab; and

then, following along these, I think the story next year will be the anti PD-L1 drugs, certainly in some indications. Those all attack immune checkpoints that are involved in the function of T-cells.

What we have definitively seen in the work that Moffitt has reported is that PV-10 elicits a T-cell response. And the translation of that into concrete results is the launching of our combination protocol using PV-10 in combination with that T-cell-based drug, pembrolizumab, the anti PD-1 drug. It's a direct descendant of that work reported, as you recall, in 2002.

So--.

Mr. Joseph Buffo: --All right. Thank you--.

Dr. Eric Wachter: --There will presumably be years and maybe decades of studies looking at nuances of how PV-10 affects the immune system. But, certainly we have a very potent initial lead that can allow us to move the goal line--move the ball forward towards the goal line in getting PV-10 approved for an indication in melanoma.

Mr. Joseph Buffo: Thank you. I appreciate it.

Mr. Peter Culpepper: From a--the CFO/COO perspective, referring to the press release we did September 23rd, we did say that the study we're doing, the 1b-2 combination study, PV-10 with pembrolizumab, is scientifically and commercially important.

So, when we're going back to the prior question of Joe Leo, the reason this is so critical for the industry is we know we had the joint patent with Pfizer. That's the first key step. We also now know that we had this 1b-2 combination study that has commenced. We're treating patients with PV-10 in combination with pembrolizumab.

Mr. Joseph Buffo: Um-hmm.

Mr. Peter Culpepper: That's the second step. And the third is the immune mechanism of action clinical study, which you and Eric were just discussing. That's been underway at Moffitt Cancer Center, and they obviously completed recruitment.

So, looking at these three key steps, what's critically important to keep in mind as it goes to pillar number five is that we are now generating meaningful clinical data to, we believe, advance the commercial importance to Provectus of how PV-10 can be optimized and the use of--.

Mr. Joseph Buffo: --Um-hmm--.

Mr. Peter Culpepper: --PV-10. And that's what is especially exciting for us to keep in mind as we are focused on our intellectual property, the mechanism data, and the key clinical studies' designs and their activation literally in this past quarter. So, this is a critical time--.

Mr. Joseph Buffo: --Thank you, Pete and Eric--.

Mr. Peter Culpepper: --For us.

Mr. Joseph Buffo: Thank you.

Mr. Peter Culpepper: And we're very excited that we can be this point. So, thanks for that follow up, Joe.

Operator: Thank you. As a reminder, if you'd like to be placed in the question queue, please press star-one at this time. If you're on a speakerphone, it may be necessary to pick up your handset before pressing star-one.

Once again, that's star-one to be placed in the question queue. Also, in the interest of time, if you wouldn't mind just limiting yourself to one question and then returning to queue for follow ups.

Our next question today is coming from Bruce Binzel [sp], a private investor. Please proceed with your question.

Mr. Bruce Binzel: Good afternoon, gentlemen. On other conference calls, it's common to get financial guidance for the next quarter. Eric--or, excuse me, Pete, can you give us guidance as to what cash burn you expect for fourth quarter 2015 and the total operating expense for the quarter?

Mr. Peter Culpepper: What we do--thank you for the question, Bruce. What we do, though, is we just comment in our MD&A on--as you are referencing, on the cash position of the company.

And the--and if we all refer to the MD&A, which we filed in the 10-Q for third quarter this morning, what we report there is that we have adequate cash in order for us to continue operations into 2017. That's the way that we have disclosed it, and I think that's what we need to keep in mind as particularly relevant.

It's very, very important to remember that we are operating closely with the New York Stock Exchange and BDO as we present this information in the 10-Q and as we continue to operate. But, we do not give monthly cash burn or quarterly cash burn within any particular filing period. We only state that we have more than 12 months cash at all times.

We also--and a key point related to this, we have considerable discretion over our variable expenses. We have very few fixed expenses, so we have considerable discretion on how we utilize expenditures. So, cash can go down and go up depending on different factors.

As a matter of fact, if you notice in the MD&A filing just this morning, we referenced the increase in the lab supplies and pharmaceutical preparations for Q3. That's particularly related to the drug supply and product.

So, we have certain expenditures that hit that are unusual in nature in a particular quarter. And that's an example, where we actually expended due to a production run for commercial grade drug supply product for purposes of the PV-10 studies that we've been discussing. That's the best way I can--.

Mr. Bruce Binzel: --So, you would--.

Mr. Peter Culpepper: --Address this, Bruce.

Mr. Bruce Binzel: Do you expect the expense level to go down next quarter to the--closer to the level of second quarter?

Mr. Peter Culpepper: We don't--again, we don't comment on a quarter by quarter. My comment here is there are certain anomalies that occur quarter by quarter; as an example, the drug supply and product.

That's--what's--I think we should keep in mind that we have the--always will have the adequate cash to meet the requirement of having more than 12 months of cash for operations. That's the most important metric, in conjunction with what we've stated for the first time on this call, having above $6 million in stockholder equity.

So, a good way to think about this is stockholder equity, $6 million as a floor, and then always having enough cash for more than 12 months. We'll have--I know this is a sensitive topic and I know it's challenging. No one wants dilution. We all want to find non-dilutive sources of cash. We will continue to work as we are on the key focus areas to advance this, but that's how we've disclosed it.

Mr. Bruce Binzel: Just to confirm, so that's a double floor. You have to have both the 12 month cash and the $6 million of equity.

Mr. Peter Culpepper: Well, a six million dollar equity--stockholder equity is a New York Stock Exchange requirement. The 12 months requirement is your typical going concern.

But remember, as I've said, we have considerable discretion over the expenses. We have very few fixed expenses. So, there's a considerable discretion, which is why we have significant latitude in our cash burn.

So, it's both together. They're not directly related, but they are very much interrelated.

Mr. Bruce Binzel: Thank you.

Operator: Thank you. As a reminder, if you'd like to be placed in the question queue, please press star-one at this time. One moment, please, while we poll for further questions.

We have reached the end of our question and answer session. I'd like to turn the floor back over to management for any further or closing comments.

Mr. Peter Culpepper: Thank you, operator.

As we wrap up this call, I want to point out this has been another very important quarter for Provectus, as we continue to develop our intellectual property portfolio, lead our investigational drugs through the FDA regulatory process, and work to develop partnerships domestically and abroad to realize our presumed commercial value of PV-10 and PH-10.

The next time we speak, we should have additional public data, including updates on PV-10 studies and on the PH-10 mechanism study. And I hope we will have more news on the commercial developments at Provectus.

Thanks for listening and thanks for supporting us. Good day.

Operator: Thank you. That does conclude today's teleconference. You may disconnect your lines at this time, and have a wonderful day. We thank you for your participation today.